SAFETY DATA SHEET



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

1.1. Product identifier

Trade name or designation

of the mixture

SENSODYNE MULTIACTION ISOACTIVE FOAM

Registration number

REINDEER BRIDGE * SENSODYNE BLACK REINDEER * MFC 02387 * SENSODYNE **Synonyms**

PRONAMEL AEROSOL * SENSODYNE PRONAMEL ACTIVE TOOTHGEL * MFC 02439 *

SODIUM FLUORIDE AND POTASSIUM NITRATE, FORMULATED PRODUCT

Issue date 19-September-2014

Version number

Revision date 19-September-2014

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

Identified uses **Oral Care**

No other uses are advised. Uses advised against

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

CAS-No. / EC No. REACH Registration No. INDEX No. Chemical name 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** 601-085-00-2 # 1 - < 3 78-78-4 201-142-8 DSD: F+;R12, Xn;R65, R66-67, N;R51/53 C Classification: CLP: Flam. Liq. 1;H224, Asp. Tox. 1;H304, STOT SE 3;H336, Aquatic Chronic 2;H411 TEGO BETAIN CK D 1 - < 361789-40-0 263-058-8 Classification: **DSD:** N;R50-51/53 CLP: Aquatic Acute 1;H400, Aquatic Chronic 2;H411 **CARVONE** 2244-16-8 < 1 218-827-2 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

s 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

Foam. Dry chemical powder. Carbon dioxide (CO2).

media

Unsuitable extinguishing Water.

media

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 Self-contained breathing apparatus and full protective clothing must be worn in case of fire. **equipment for firefighters**

Material name: SENSODYNE MULTIACTION ISOACTIVE FOAM

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

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

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

sections

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

(ż	S	K

Components	Туре	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	

UK. EH40 Workplace Exposure Limits (WELs)

Components	Туре	Value	Form
GLYCERIN (CAS 56-81-5)	TWA	10 mg/m3	Mist.
ISOPENTANE (CAS 78-78-4)	TWA	1800 mg/m3	
•		600 ppm	
SIDENT (CAS 7631-86-9)	TWA	6 mg/m3	Inhalable dust.
		2.4 mg/m3	Respirable dust.
ZEODENT 113 (CAS 112926-00-8)	TWA	6 mg/m3	Inhalable dust.
•		2.4 mg/m3	Respirable dust.

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
10-10 -4)		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.

Material name: SENSODYNE MULTIACTION ISOACTIVE FOAM

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).

Hygiene measures

Thermal hazards

Wear appropriate thermal protective clothing, when necessary.

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. Not available. **Odour threshold** Not available. pН Melting point/freezing point Not available. Initial boiling point and boiling Not available.

range

Flash point 25 °C (77 °F) Closed cup

Not available. **Evaporation rate** 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 Not available. Vapour density Not available. Relative density

Solubility(ies)

Not available. Solubility (water) Solubility (other) Not available. Not available. Partition coefficient

(n-octanol/water)

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

Material name: SENSODYNE MULTIACTION ISOACTIVE FOAM

ViscosityNot available.Explosive propertiesNot available.Oxidizing propertiesNot 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. ReactivityThe 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 avoidKeep 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

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

decomposition products

SECTION 11: Toxicological information

General information Occupational exposure to the substance or mixture may cause 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. 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.

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

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

Serious eye damage/eye Direct contact with eyes may cause temporary irritation.

irritation

Respiratory sensitisation Not available.

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

Germ cell mutagenicityNo 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.

Reproductive toxicity Health injuries are not known or expected under normal use. Contains no ingredient listed as toxic

to reproduction

Material name: SENSODYNE MULTIACTION ISOACTIVE FOAM

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

Specific target organ toxicity -

single exposure

None known.

Specific target organ toxicity -

repeated exposure

None known.

Not available.

Aspiration hazard

Mixture versus substance

information

No information available.

Not available. Other information

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			
Acute			
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	6 61789-40-0)		
Aquatic			
Acute			
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
Chronic			
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 111	138-66-2)		
Aquatic	•		
Acute			
Fish	EC50	Rainbow trout (Adult Oncorhyncus mykiss)	420 mg/l, 96 hours Static test

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

12.2. Persistence and

No data is available on the degradability of this product.

degradability

Photolysis

Half-life (Photolysis-atmospheric)

2.7 Hours Estimated **CARVONE**

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 Not available.

and vPvB assessment

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 codeThe 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 precautionsDispose 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 Aerosols, non-flammable, (each not exceeding 1 L capacity)

name

14.3. Transport hazard class(es)

Class 2.2 Subsidiary risk -Label(s) 2.2

Hazard No. (ADR)
Not available.
Not available.
14.4. Packing group
Not applicable.

14.5. Environmental hazards No.

14.6. Special precautions Not available.

for user

IATA

14.1. UN number UN1950

14.2. UN proper shipping Aerosols, non-flammable

name

14.3. Transport hazard 2.2

class(es)

۷.۷

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

Other information

Cargo aircraft only Allowed.

Additional Information:

Passenger & cargo Allowed.

IMDG

14.1. UN number UN1950

14.2. UN proper shipping AEROSOLS, asphyxiant

Not available.

name

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 Not available.

for user

14.7. Transport in bulk ACCORDING TO Annex II ofMARPOL 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.

MARPOL73/78 and the IBC Code

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.

Material name: SENSODYNE MULTIACTION ISOACTIVE FOAM

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

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

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 No Chemical Safety Assessment has been carried out.

assessment

SECTION 16: Other information

List of abbreviations Not available

GSK Hazard Determination References

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 eves 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.

Product and Company Identification: Product and Company Identification Revision information

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.

Material name: SENSODYNE MULTIACTION ISOACTIVE FOAM

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.

Material name: SENSODYNE MULTIACTION ISOACTIVE FOAM