

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

1.1. Product identifier

Trade name or designation of the mixture	ENO LEMON LOCAL
Registration number	-
Synonyms	SODIUM BICARBONATE, FORMULATED PRODUCT
Issue date	20-November-2012
Version number	01
Revision date	20-November-2012
Supersedes date	-

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

Identified uses Medicinal Product

This safety data sheet is written to provide health, safety and environmental information for people handling this formulated product in the workplace. It is not intended to provide information relevant to medicinal use of the product. In this instance patients should consult prescribing information/package insert/product label or consult their pharmacist or physician. For health and safety information for individual ingredients used during manufacturing, refer to the appropriate safety data sheet for each ingredient.

Uses advised against No other uses are advised.

1.3. Details of the supplier of the safety data sheet

GlaxoSmithKline UK
980 Great West Road
Brentford, Middlesex TW8 9GS UK
UK General Information (normal business hours): +44-20-8047-5000
Email Address: msds@gsk.com
Website: www.gsk.com

1.4. Emergency telephone number

TRANSPORT EMERGENCIES (by country / geographic region):
Africa / EU / Israel / Middle East
(English / European languages): +44 (0) 1235 239 670
Asia Pacific (except China): +65 3158 1074
China: +86 10 5100 3039
Middle East / Africa (Arabic-speaking countries): +44 (0) 1235 239 671
United States: +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 Not applicable.

2.3. Other hazards

Assume that this material is capable of sustaining combustion.
Assume that this material is capable of producing a dust explosion if ignited as a dust cloud.
Assume that this material is capable of being ignited by an electrostatic discharge.
Not expected to be a health hazard during normal handling.
Health effects information is based on hazards of components.
No information is available about the potential of this product to produce adverse environmental effects.

SECTION 3: Composition/information on ingredients

3.1. Mixtures

General information

Chemical name	%	CAS-No. / EC No.	REACH Registration No.	INDEX No.	Notes
SODIUM BICARBONATE	45.0 - 48.0	144-55-8 205-633-8	-	-	
Classification:	DSD: -				
	CLP: -				
CITRIC ACID ANHYDROUS	43.0 - 45.0	77-92-9 201-069-1	-	-	
Classification:	DSD: Xi;R36				
	CLP: Skin Corr. 1;H314, Eye Irrit. 2;H319				
Sodium carbonate	10	497-19-8 207-838-8	-	011-005-00-2	
Classification:	DSD: Xi;R36				
	CLP: Eye Irrit. 2;H319				

Other components below reportable levels <3.0

SECTION 4: First aid measures

General information

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	In case of accident by inhalation: remove casualty to fresh air and keep at rest. If breathing is difficult, trained personnel should give oxygen. If not breathing, give artificial respiration. Get medical attention immediately.
Skin contact	Immediately flush with plenty of water for at least 15 minutes while removing contaminated clothing and shoes. Remove and isolate contaminated clothing and shoes. Get medical attention immediately.
Eye contact	In the case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
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 unconscious person.

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

Not available.

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 local poison control information centre.

SECTION 5: Firefighting measures

General fire hazards

Assume that this material is capable of sustaining combustion.

5.1. Extinguishing media

Suitable extinguishing media Water. Dry powder. Foam.

Unsuitable extinguishing media Carbon dioxide (CO₂).

5.2. Special hazards arising from the substance or mixture

Toxic, corrosive or flammable thermal decomposition products are expected when the product is exposed to fire.

5.3. Advice for firefighters

Special protective equipment for firefighters Since toxic, corrosive or flammable vapours might be evolved from fires involving this material, self contained breathing apparatus and full protective equipment are recommended for firefighters.

Special fire fighting procedures For single units (packages): No special requirements needed.
For larger amounts (multiple packages/pallets) of product: Since toxic, corrosive or flammable vapours might be evolved from fires involving this product and associated packaging, self contained breathing apparatus and full protective equipment are recommended for firefighters. If possible, contain and collect firefighting water for later disposal.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

For non-emergency personnel Wear protective clothing and equipment consistent with the degree of hazard.

For emergency responders Use personal protection recommended in Section 8 of the MSDS.

6.2. Environmental precautions For large spills, take precautions to prevent entry into waterways, sewers, or surface drainage systems.

6.3. Methods and material for containment and cleaning up Collect and place it in a suitable, properly labelled container for recovery or disposal. No specific decontamination or detoxification procedures have been identified for this product.

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 Follow all MSDS/label precautions even after container is emptied because they may retain product residues.

7.2. Conditions for safe storage, including any incompatibilities Room temperature - normal conditions. Keep away from heat and sources of ignition. Store in tightly closed original container in a well-ventilated place.

7.3. Specific end use(s) Medicinal Product

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Occupational exposure limits

GSK

Components	Type	Value
CITRIC ACID ANHYDROUS (77-92-9)	8 HR TWA	5000 mcg/m3
	OHC	1
SODIUM BICARBONATE (144-55-8)	8 HR TWA	5000 mcg/m3
	OHC	1
Sodium carbonate (497-19-8)	8 HR TWA	5000 mcg/m3
	OHC	1

United Kingdom

No exposure limits noted for the ingredient(s).

Biological limit values

EU

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

United Kingdom

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

Recommended monitoring procedures Not available.

Derived No Effect Level (DNEL) Not available.

Predicted no effect concentrations (PNECs) Not available.

8.2. Exposure controls

Appropriate engineering controls No special engineering controls are required.

Individual protection measures, such as personal protective equipment

General information An eye wash station should be available.

Eye/face protection Wear approved safety glasses with side shields if eye contact is possible. (eg. EN 166)

Skin protection

- Hand protection None required for the normal handling of this material.

- Other None known.

Respiratory protection No personal respiratory protective equipment normally required.

Thermal hazards Not available.

Hygiene measures Wash hands and arms thoroughly after handling.

Environmental exposure controls

Hazard guidance and control recommendations Not available.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance

Physical state	Solid.
Form	Powder.
Colour	Not available.
Odour	Not available.
Odour threshold	Not available.
pH	Not applicable.
Melting point/freezing point	Not available.
Initial boiling point and boiling range	Not available.
Flash point	Not applicable.
Evaporation rate	Not applicable.
Flammability (solid, gas)	Not applicable.

Upper/lower flammability or explosive limits

Flammability limit - lower (%)	Not available.
Flammability limit - upper (%)	Not available.
Explosive limit - lower (%)	Not available.
Explosive limit – upper (%)	Not available.
Vapour pressure	Not applicable.
Vapour density	Not applicable.
Relative density	Not available.
Solubility(ies)	Not available.
Partition coefficient (n-octanol/water)	Not available.
Decomposition temperature	Not available.
Viscosity	Not applicable.
Explosive properties	Not available.
Oxidizing properties	Not available.

9.2. Other information

Dust explosion properties

St class	No studies have been conducted.
Minimum Ignition Energy (MIE) - dust cloud	No studies have been conducted.
Train fire	No studies have been conducted.

SECTION 10: Stability and reactivity

10.1. Reactivity	Not available.
10.2. Chemical stability	This product is expected to be stable.
10.3. Possibility of hazardous reactions	Not available.
10.4. Conditions to avoid	None for normal handling of this product.
10.5. Incompatible materials	Not available.
10.6. Hazardous decomposition products	Toxic, corrosive or flammable thermal decomposition products are expected when the product is exposed to fire.

SECTION 11: Toxicological information

General information Not available.

Information on likely routes of exposure

Ingestion	Not expected to be toxic following ingestion.
Inhalation	None known.
Skin contact	None known.
Eye contact	May be irritating to eyes.

Symptoms None known.

11.1. Information on toxicological effects

Acute toxicity Not expected to be toxic following ingestion.

Components	Species	Test results
CITRIC ACID ANHYDROUS (77-92-9)		
Acute		
<i>Oral</i>		
LD50	Rat	3000 mg/kg
SODIUM BICARBONATE (144-55-8)		
Acute		
<i>Oral</i>		
LD50	Rat	4220 mg/kg
Sodium carbonate (497-19-8)		
Acute		
<i>Inhalation</i>		
LC50	Rat	2.3 mg/l
<i>Oral</i>		
LD50	Rat	6600 mg/kg
Skin corrosion/irritation	None known.	
Serious eye damage/eye irritation	May be irritating to eyes.	
Respiratory sensitisation	None known.	
Skin sensitisation	None known.	
Germ cell mutagenicity	Not expected to be genotoxic under occupational exposure conditions.	
Carcinogenicity	None known.	
Reproductive toxicity	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	No studies have been conducted.	
Mixture versus substance information	No studies have been conducted.	
Other information	None known.	

SECTION 12: Ecological information

12.1. Toxicity No information is available about the potential of this material to produce adverse environmental effects. Local regulations and procedures should be consulted prior to environmental release.

Components	Species	Test results
CITRIC ACID ANHYDROUS (77-92-9)		
Aquatic		
<i>Acute</i>		
Crustacea	EC50	Water flea (Daphnia magna) 120 mg/l, 72 hours, Static test
Fish	EC50	Bluegill sunfish (Adult Lepomis macrochirus) 1516 mg/l, 96 hours, Static test
		Golden ide/orfe (Adult Leuciscus idus) 440 - 760 mg/l, 96 hours, Static test
Microtox	EC50	Microtox 14 mg/l, 15 minutes

Components		Species	Test results
SODIUM BICARBONATE (144-55-8)			
Aquatic			
<i>Acute</i>			
Algae	EC50	Algae (Nitscheria linearis)	650 mg/l, 5 days
Crustacea	EC50	Water flea (Daphnia magna)	2350 mg/l, 48 hours, Static test
Fish	EC50	Bluegill sunfish (Adult Lepomis macrochirus)	8250 - 9000 mg/l, 96 hours, Static test
		Mosquito fish (Adult Gambusia affinis)	7550 mg/l, 96 hours, Static test
Sodium carbonate (497-19-8)			
Aquatic			
<i>Acute</i>			
Algae	EC50	Green algae (Selenastrum capricornutum)	> 800 mg/l
Crustacea	EC50	Water flea (Daphnia magna)	265 mg/l, 48 hours, Static test
Fish	EC50	Bluegill sunfish (Adult Lepomis macrochirus)	300 mg/l, 96 hours, Static test
		Fathead minnow (Juvenile Pimephales promelas)	< 850 mg/l, 96 hours, Static test
		Mosquito fish (Adult Gambusia affinis)	740 mg/l, 96 hours, Static test

12.2. Persistence and degradability

Biodegradability

Percent degradation (Aerobic biodegradation-inherent)

CITRIC ACID ANHYDROUS 98 %, 2 days Modified Zahn-Wellens, Activated sludge

12.3. Bioaccumulative potential Not available.

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

12.4. Mobility in soil

Mobility in general

Volatility

Henry's law

CITRIC ACID ANHYDROUS < 0 atm m³/mol Calculated, 25 °C

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 Not available.

Contaminated packaging Not available.

EU waste code Not available.

Disposal methods/information Observe all local and national regulations when disposing of this product. Collect for recycling or recovery if possible. The disposal method for rejected products/returned goods must ensure that they cannot be re-sold or re-used.

SECTION 14: Transport information

The SDS should accompany all shipments for reference in the event of spillage or accidental release. Only authorised persons trained and competent in accordance with appropriate national and international regulatory requirements may prepare dangerous goods for transport.

ADR

Not regulated as dangerous goods.

IATA

Not regulated as dangerous goods.

IMDG

Not regulated as dangerous goods.

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. 143/2011 Annex XIV Substances Subject to Authorisation

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

Not listed.

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

Not listed.

Other EU regulations

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

Not listed.

National regulations Not available.

15.2. Chemical safety assessment Not available.

SECTION 16: Other information

List of abbreviations Not available.

References GSK Hazard Determination

Information on evaluation method leading to the classification of mixture Not available.

Full text of any statements or R-phrases and H-statements under Sections 2 to 15

R36 Irritating to eyes.
H314 - Causes severe skin burns and eye damage.
H319 - Causes serious eye irritation.

Revision information Composition/Information on Ingredients: Ingredients
Physical & Chemical Properties: Multiple Properties

Training information Not available.

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.

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