

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

### 1.1. Product identifier

Trade name or designation of the mixture	ENO REGULAR LOCAL
Registration number	-
Synonyms	ENO NORMAL MEZCLA / ENO NORMAL MEZCLA PORTUGAL JBL * SODIUM BICARBONATE, FORMULATED PRODUCT
Issue date	05-August-2013
Version number	02
Revision date	05-August-2013
Supersedes date	20-November-2012

### 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](mailto:msds@gsk.com)  
Website: [www.gsk.com](http://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** 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

### 3.2. 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	-	-	
<b>Classification:</b>	<b>DSD:</b> -				
	<b>CLP:</b> -				
CITRIC ACID ANHYDROUS	43.0 - 45.0	77-92-9 201-069-1	-	-	
<b>Classification:</b>	<b>DSD:</b> Xi;R36				
	<b>CLP:</b> Eye Irrit. 2;H319				
Sodium carbonate	10	497-19-8 207-838-8	-	011-005-00-2	
<b>Classification:</b>	<b>DSD:</b> Xi;R36				
	<b>CLP:</b> Eye Irrit. 2;H319				

Other components below reportable levels 1.0

## 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

<b>Inhalation</b>	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.
<b>Skin contact</b>	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.
<b>Eye contact</b>	In the case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
<b>Ingestion</b>	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

<b>Suitable extinguishing media</b>	Water. Dry powder. Foam.
<b>Unsuitable extinguishing media</b>	Carbon dioxide (CO <sub>2</sub> ).

**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

<b>Special protective equipment for firefighters</b>	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.
<b>Special fire fighting procedures</b>	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 (CAS 77-92-9)	8 HR TWA	5000 mcg/m3
	OHC	1
SODIUM BICARBONATE (CAS 144-55-8)	8 HR TWA	5000 mcg/m3
	OHC	1
Sodium carbonate (CAS 497-19-8)	8 HR TWA	5000 mcg/m3
	OHC	1

**Biological limit values** 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

Material name: ENO REGULAR LOCAL

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<b>Physical state</b>	Solid.
<b>Form</b>	Powder.
<b>Colour</b>	Not available.
<b>Odour</b>	Not available.
<b>Odour threshold</b>	Not available.
<b>pH</b>	Not available.
<b>Melting point/freezing point</b>	Not available.
<b>Initial boiling point and boiling range</b>	Not available.
<b>Flash point</b>	Not available.
<b>Evaporation rate</b>	Not available.
<b>Flammability (solid, gas)</b>	Not available.
<b>Upper/lower flammability or explosive limits</b>	
<b>Flammability limit - lower (%)</b>	Not available.
<b>Flammability limit - upper (%)</b>	Not available.
<b>Vapour pressure</b>	Not available.
<b>Vapour density</b>	Not available.
<b>Relative density</b>	Not available.
<b>Solubility(ies)</b>	Not available.
<b>Partition coefficient (n-octanol/water)</b>	Not available.
<b>Auto-ignition temperature</b>	Not available.
<b>Decomposition temperature</b>	Not available.
<b>Viscosity</b>	Not available.
<b>Explosive properties</b>	Not available.
<b>Oxidizing properties</b>	Not available.

## 9.2. Other information

### Dust explosion properties

<b>St class</b>	No studies have been conducted.
<b>Minimum Ignition Energy (MIE) - dust cloud</b>	No studies have been conducted.

<b>Train fire</b>	No studies have been conducted.
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## SECTION 10: Stability and reactivity

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

## SECTION 11: Toxicological information

<b>General information</b>	Not available.
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### Information on likely routes of exposure

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

<b>Symptoms</b>	None known.
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## 11.1. Information on toxicological effects

**Acute toxicity** Not expected to be toxic following ingestion.

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

<b>Components</b>	<b>Species</b>	<b>Test results</b>
CITRIC ACID ANHYDROUS (CAS 77-92-9)		
<b>Aquatic</b>		
<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
SODIUM BICARBONATE (CAS 144-55-8)		
<b>Aquatic</b>		
<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

Components	Species	Test results
Sodium carbonate (CAS 497-19-8)		
<b>Aquatic</b>		
<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

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

12.4. Mobility in soil Not available.

### Mobility in general

#### Volatility

##### Henry's law

CITRIC ACID ANHYDROUS < 0 atm m<sup>3</sup>/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

<b>Residual waste</b>	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).
<b>Contaminated packaging</b>	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.
<b>EU waste code</b>	The Waste code should be assigned in discussion between the user, the producer and the waste disposal company.
<b>Disposal methods/information</b>	Collect and reclaim or dispose in sealed containers at licensed waste disposal site. 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.
<b>Special precautions</b>	Dispose in accordance with all applicable regulations.

## SECTION 14: Transport information

**General** 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.

**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.

## 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**

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.

**Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work**

Sodium carbonate (CAS 497-19-8)

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

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.

H319 Causes serious eye irritation.

#### Revision information

Product and Company Identification: Synonyms

SECTION 13: Disposal considerations: Disposal methods/information

SECTION 13: Disposal considerations: Residual waste

SECTION 13: Disposal considerations: Contaminated packaging

SECTION 13: Disposal considerations: EU waste code

SECTION 13: Disposal considerations: Special precautions

**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.