

SAFETY DATA SHEET

SECTION 1: IDENTIFICATION OF THE MIXTURE AND OF THE COMPANY/UNDERTAKING

- 1.1. **Product identifier:**
Astroplast Sterile Solution
- 1.2. **Relevant identified uses of the mixture and uses advised against:**
Solution for eye irrigation only, for consumer use.
- 1.3. **Details of the supplier of the safety data sheet:**

Information about the manufacturer:
Wallace Cameron International
26 Netherhall Road, Netherton Industrial Estate, Wishaw, ML2 0JG
Tel: 01698 354600
- 1.3.1. Responsible person: Quality and Regulatory Manager
E-mail: sales@wallacecameron.com
- 1.4. **Emergency telephone number:** 01698 354600

SECTION 2: HAZARDS IDENTIFICATION

- 2.1. **Classification of the mixture:**

Classification according to Regulation (EC) No 1272/2008 (CLP):

Not considered as hazardous mixture.

Hazard statements: No hazard statements.
- 2.2. **Label elements:**

Hazard statements: No hazard statements.

Precautionary statements: No precautionary statements.
- 2.3. **Other hazards:**
The product has no other known specific hazards for human or environment.
Results of PBT and vPvB assessment: No data available.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

- 3.1. **Substances:**
Not applicable.
- 3.2. **Mixtures:**

Description	CAS number	EC number / ECHA list number	REACH registration number	Conc. (%)	Classification according to Regulation (EC) No 1272/2008 (CLP)		
					Pictogram, signal word code(s)	Hazard class and category code(s)	Hazard statement code(s)
Sodium chloride*	7647-14-5	231-598-3	-	0.9	-	not classified	-
Water	7732-18-5	231-791-2	-	99.1	-	not classified	-

*: Classification specified by the manufacturer; the substance is not listed in Annex VI of the Regulation (EC) No 1272/2008.

For the full text of hazard statements, see Section 16.

SECTION 4: FIRST AID MEASURES

4.1. Description of first aid measures:

General information: In case of normal use, special measures are not required. In case of long term, industrial production, refer to the following:

INGESTION:

Measures:

- Do not induce vomiting.
- Call a physician.

INHALATION:

Measures:

- Take the victim into fresh air.

SKIN CONTACT:

Measures:

- Wash the skin with water and soap.

EYE CONTACT:

Measures:

- In case of contact with eyes flush with water holding eyelids apart (for at least 15 minutes).

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

No acute and delayed symptoms and effects known.

4.3. Indication of any immediate medical attention and special treatment needed:

No special treatment needed; treat symptomatically.

SECTION 5: FIREFIGHTING MEASURES

5.1. Extinguishing media:

5.1.1. Suitable extinguishing media:

Choose extinguishing media depending on surrounding fire, such as dry powder, carbon dioxide.

5.1.2. Unsuitable extinguishing media:

No data available.

5.2. Special hazards arising from the substance or mixture:

In case of fire, smoke and other combustion products may be formed; the inhalation of such combustion products can have serious adverse effects on health.

5.3. Advice for firefighters:

Wear full protective clothing and self-contained breathing apparatus.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures:

6.1.1. For non-emergency personnel:

Allow only well-trained experts wearing suitable protective clothing to abide in the field of accident.

6.1.2. For emergency responders:

In case of normal use, special measures are not required. In case of long term, industrial production, refer to the following:

Wear appropriate personal protective equipment.

Keep unprotected persons away.

Ensure adequate ventilation.

Remove ignition sources, evacuate the area.

6.2. Environmental precautions:

Dispose of the spillage and the resulting waste according to the applicable environmental regulations. Do not allow the product and the resulting waste to enter sewers/soil/surface or ground water. Notify the respective authorities in accordance with local law in the case of environmental pollution immediately.

6.3. Methods and material for containment and cleaning up:

Collect the spilled product with absorbent, then place into a suitable, closed, properly labelled chemical waste container for removal/disposal.

Avoid releasing into sewers, ditches and water bodies.

- 6.4. **Reference to other sections:**
 For further and detailed information see Sections 7, 8 and 13.

SECTION 7: HANDLING AND STORAGE

In case of normal use, special measures are not required. In case of long term, industrial production, refer to the following:

- 7.1. **Precautions for safe handling:**
 Observe conventional hygiene precautions.
 Wash hands thoroughly before eating and drinking.
Technical measures:
 Store in a cold, dry and well-ventilated environment.
 Keep away from food and water supplies.
 Keep away from incompatible materials, such as strong oxidizing agents.
Precautions against fire and explosion:
 Prevent the generation and accumulation of static electricity when handling the container.
- 7.2. **Conditions for safe storage, including any incompatibilities:**
Technical measures and storage condition:
 Store in a cool place.
 Keep container closed in a cool, dry and well-ventilated place.
Incompatible materials: See Section 10.5
Packaging material: No special prescriptions.
- 7.3. **Specific end use(s):**
 No specific instructions available.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

- 8.1. **Control parameters:**

Occupational exposure limit values (EH₄₀/2005 Workplace exposure limits):
 The components of the mixture are not regulated with exposure limit value.

DNEL values		Oral exposure		Dermal exposure		Inhalative exposure	
		Short term (acute)	Long term (chronic)	Short term (acute)	Long term (chronic)	Short term (acute)	Long term (chronic)
Consumer	Local	no data	no data	no data	no data	no data	no data
	Systemic	no data	no data	no data	no data	no data	no data
Worker	Local	no data	no data	no data	no data	no data	no data
	Systemic	no data	no data	no data	no data	no data	no data

PNEC values		
Compartment	Value	Note(s)
Freshwater	no data	no notes
Marine water	no data	no notes
Freshwater sediment	no data	no notes
Marine water sediment	no data	no notes
Sewage Treatment Plant (STP)	no data	no notes
Intermittent release	no data	no notes
Secondary poisoning	no data	no notes
Soil	no data	no notes

- 8.2. **Exposure controls:**
 In case of a hazardous material with no controlled concentration limit it is the employer's duty to keep concentration levels down to a minimum achievable by existing scientific and technological means, where the hazardous substance poses no harm to workers.
- 8.2.1. **Appropriate engineering controls:**
 In pursuance of work is proper foresight needed to avoid leaking onto clothes and floors and to avoid contact with eyes and skin.
- 8.2.2. **Individual protection measures, such as personal protective equipment:**
 Observe the general safety regulations when handling chemicals.

Keep away from food, beverage and feed.
Remove all soiled and contaminated clothing immediately.
Wash hands before breaks and at the end of work.

1. **Eye/face protection:** Use appropriate protective glasses (EN 166).
2. **Skin protection:**
 - a. **Hand protection:** Use appropriate protective gloves (EN 374).
 - b. **Other:** In case of large leakage use appropriate protective clothing. Take into account the concentration and the quantity of hazardous substances.
3. **Respiratory protection:** Use appropriate protective mask to reduce exposure. In case of large leakage wear self-contained breathing apparatus.
4. **Thermal hazards:** No thermal hazards known.

8.2.3. **Environmental exposure controls:**

No specific prescription.

The requirements detailed in Section 8 assume skilled work under normal conditions and usage of the product for appropriate aims. If conditions differ from normal or work is carried out under extreme conditions, an expert's advice is necessary before deciding upon further protective measures.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties:

Parameter	Value / Test method / Remarks
1. Appearance:	colourless, transparent liquid
2. Odour:	no data*
3. Odour threshold:	no data*
4. pH:	5.7 (25 °C, 70 % RH)
5. Melting point/freezing point:	no data*
6. Initial boiling point and boiling range:	no data*
7. Flash point:	>100 °C (closed cup)
8. Evaporation rate:	no data*
9. Flammability (solid, gas):	no data*
10. Upper/lower flammability or explosive limits:	no data*
11. Vapour pressure:	no data*
12. Vapour density:	no data*
13. Relative density:	no data*
14. Solubility(ies):	easily soluble in water
15. Partition coefficient: n-octanol/water:	no data*
16. Auto-ignition temperature:	no data*
17. Decomposition temperature:	no data*
18. Viscosity:	no data*
19. Explosive properties:	no data*
20. Oxidizing properties:	no data*

9.2. Other information:

No data available.

*: The manufacturer did not carry out any tests on this parameter for the product or the results of the tests are not available at the time of publication of the data sheet.

SECTION 10: STABILITY AND REACTIVITY

10.1. Reactivity:

No reactivity known.

10.2. Chemical stability:

Stable under normal conditions.

10.3. Possibility of hazardous reactions:

No hazardous reactions known.

10.4. Conditions to avoid:

Incompatible materials.

10.5. Incompatible materials:

Strong oxidizing agents.

10.6. Hazardous decomposition products:
Carbon oxides.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1. Information on toxicological effects:

Acute toxicity: Based on available data, the classification criteria are not met.

Skin corrosion/irritation: Based on available data, the classification criteria are not met.

Serious eye damage/irritation: Based on available data, the classification criteria are not met.

Respiratory or skin sensitisation: Based on available data, the classification criteria are not met.

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

Carcinogenicity: Based on available data, the classification criteria are not met.

Reproductive toxicity: Based on available data, the classification criteria are not met.

STOT-single exposure: Based on available data, the classification criteria are not met.

STOT-repeated exposure: Based on available data, the classification criteria are not met.

Aspiration hazard: Based on available data, the classification criteria are not met.

11.1.1. Summaries of the information derived from the test conducted:

No data available.

11.1.2. Relevant toxicological properties:

No data available.

11.1.3. Information on likely routes of exposure:

Ingestion, inhalation, skin contact, eye contact.

11.1.4. Symptoms related to the physical, chemical and toxicological characteristics:

No data available.

11.1.5. Delayed and immediate effects as well as chronic effects from short and long-term exposure:

Based on our experiences and the available information, in case of proper use and handling, no adverse effects on health can be expected.

11.1.6. Interactive effects:

No data available.

11.1.7. Absence of specific data:

No information.

11.1.8. Other information:

No data available.

SECTION 12: ECOLOGICAL INFORMATION

12.1. Toxicity:

The mixture is not classified as hazardous for the environment.

12.2. Persistence and degradability:

No data available.

12.3. Bioaccumulation potential:

No data available.

12.4. Mobility in soil:

No data available.

12.5. Results of PBT and vPvB assessment:

No data available.

12.6. Other adverse effects:

No data available.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods:

Disposal according to the local regulations.

13.1.1. Information regarding the disposal of the product:

Dispose of in accordance with applicable regulations.

List of Waste Code:

No waste disposal key according to the List of Waste Code (LoW code) can be determined for this product, as only the purpose of application defined by the user enables an allocation. The LoW code number has to be determined after a discussion with a waste disposal specialist.

13.1.2. Information regarding the disposal of the packaging:

Dispose of in accordance with applicable regulations.

- 13.1.3. **Physical/chemical properties that may affect waste treatment options shall be specified:**
No data available.
- 13.1.4. **Sewage disposal:**
No data available.
- 13.1.5. **Special precautions for any recommended waste treatment:**
No data available.

SECTION 14: TRANSPORT INFORMATION

ADR/RID; ADN; IMDG; IATA:
Not subject to the conventions of carriage of dangerous goods.

- 14.1. **UN Number:**
No UN Number.
- 14.2. **UN proper shipping name:**
No proper shipping name.
- 14.3. **Transport hazard class(es):**
No transport hazard classes.
- 14.4. **Packing group:**
No packing group.
- 14.5. **Environmental hazards:**
No relevant information available.
- 14.6. **Special precautions for user:**
No relevant information available.
- 14.7. **Transport in bulk according to Annex II of MARPOL and the IBC Code:**
Not applicable.

SECTION 15: REGULATORY INFORMATION

- 15.1. **Safety, health and environmental regulations/legislation specific for the substance or mixture:**

REGULATION (EC) No 1907/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive (EC) No 1999/45 and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive (EEC) No 76/769 and Commission Directives (EEC) No 91/155, (EEC) No 93/67, (EC) No 93/105 and (EC) No 2000/21

REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives (EEC) No 67/548 and (EC) No 1999/45, and amending Regulation (EC) No 1907/2006

COMMISSION REGULATION (EU) No 2015/830 of 28 May 2015 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)

- 15.2. **Chemical safety assessment:** No information.

SECTION 16: OTHER INFORMATION

Information regarding the revision of the safety data sheet: No information.

Literature references / data sources:
Safety data sheet issued by the manufacturer (23. 07. 2015, EN)

Methods used for the classification according to Regulation (EC) No 1272/2008:
Based on the calculation method carried out on the basis of the known hazards of the components, not considered as a hazardous mixture.

Relevant hazard statements (code and full text) of Sections 2 and 3: No relevant statements.

Training advice: No data available.

Full text of the abbreviations in the safety data sheet:

ADN: The European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways.
ADR: The European Agreement concerning the International Carriage of Dangerous Goods by Road.
ATE: Acute Toxicity Estimate.
AOX: Adsorbable organic halides.
BCF: Bioconcentration factor.
BOD: Biological Oxygen Demand.
CAS number: Chemical Abstract Service number.
CLP: Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures.
CMR effects: Carcinogenic, mutagenic, reprotoxic effects.
COD: Chemical Oxygen Demand.
CSA: Chemical Safety Assessment.
CSR: Chemical Safety Report.
DNEL: Derived-No-Effect-Level.
ECHA: European Chemical Agency.
EC: European Community.
EC number: EINECS and ELINCS numbers (see also EINECS and ELINCS).
EEC: European Economic Community.
EEA: European Economic Area (EU + Iceland, Liechtenstein and Norway).
EINECS: European Inventory of Existing Commercial Chemical Substances.
ELINCS: European List of Notified Chemical Substances.
EN: European Norm.
EU: European Union.
EWC: European Waste Catalogue (replaced by LoW – see below).
GHS: Globally Harmonized System of Classification and Labelling of Chemicals.
IATA: International Air Transport Association.
ICAO-TI: Technical Instructions for the Safe Transport of Dangerous Goods by Air.
IMDG: International Maritime Dangerous Goods.
IMSBC: International Maritime Solid Bulk Cargoes.
IUCLID: International Uniform Chemical Information Database.
IUPAC: International Union of Pure and Applied Chemistry.
Kow: n-Octanol - Water Partition Coefficient.
LC₅₀: Lethal concentration resulting in 50 % mortality.
LD₅₀: Lethal dose resulting in 50 % mortality (median lethal dose).
LoW: List of Waste.
LOEC: Lowest Observed Effect Concentration.
LOEL: Lowest Observed Effect Level.
NOEC: No Observed Effect Concentration.
NOEL: No Observed Effect Level.
NOAEC: No Observed Adverse Effect Concentration.
NOAEL: No Observed Adverse Effect Level.
OECD: Organization for Economic Cooperation and Development.
OSHA: Occupational Safety and Health Administration.
PBT: Persistent, Bioaccumulative and Toxic.
PNEC: Predicted No Effect Concentration.
QSAR: Quantitative Structure Activity Relationship.
REACH: Regulation 1907/2006/EC concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals.
RID: Regulations Concerning the International Transport of Dangerous Goods by Rail.
SCBA: Self Contained Breathing Apparatus.
SDS: Safety Data Sheet.
STOT: Specific Target Organ Toxicity.
SVHC: Substances of Very High Concern.
UN: United Nations.
UVCB: Chemical Substances of Unknown or Variable Composition, Complex Reaction Products and Biological Materials.
VOC: Volatile Organic Compound.
vPvB: very Persistent and very Bioaccumulative.

This safety data sheet had been prepared on the basis of information provided by the manufacturer/supplier and conform to the relevant regulations.

The information, data and recommendations contained herein are provided in good faith, obtained from reliable sources and believed to be true and accurate as of the date issued; however, no representation is made as to the comprehensiveness of the information.

The SDS shall be used only as a guide for handling the product; in the course of handling and using the product other considerations may arise or be required.

Users are cautioned to determine the appropriateness and applicability of the above information to their particular circumstances and purposes and assume all risk associated with the use of this product.

It is the responsibility of the user to fully comply with local, national and international regulations concerning the use of this product.

Safety data sheet was prepared by:
MSDS-Europe
International branch of ToxInfo Kft.

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