Date of revision: -

### SAFETY DATA SHEET

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

### 1.1. <u>Product identifier:</u>

**Astroplast Burn Kool Dressing** 

# 1.2. Relevant identified uses of the mixture and uses advised against:

Can be used to treat minor burns, scalds or sunburn, for consumer use.

### 1.3. <u>Details of the supplier of the safety data sheet:</u>

Information about the manufacturer:

Wallace Cameron International

26 Netherhall Road, Netherton Industrial Estate, Wishaw, ML2 oJG

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. <u>Classification of the mixture:</u>

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

Not considered as hazardous mixture.

**Hazard statements:** No hazard statements.

### 2.2. <u>Label elements:</u>

Hazard statements: No hazard statements.

**Precautionary statements:** No precautionary statements.

### Attention!

Do not use the product or material in vivo or directly in the blood pathway, because the product does not have further clinical validation with regards of in vivo or blood pathway application, and there is no guarantee for explanation, promise or implication for in vivo transplantation.

### 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:

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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)
Siloxanes and Silicones, Me Ph*	63148-58-3	613-153-9	-	1	-	not classified	
Propane-1,2- diol*/**	57-55-6	200-338-0	-	4	-	not classified	
Glycerol*/**	56-81-5	200-289-5	-	4	-	not classified	
Laurocapram*	59227-89-3	261-668-9	-	1	-	not classified	
Pure water	7732-18-5	231-791-2	-	89	-	not classified	

<sup>\*:</sup> 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:**

### **INGESTION:**

Measures:

Immediately call a physician.

# **INHALATION:**

Measures:

Take the victim into fresh air.

# **SKIN CONTACT:**

Measures:

- Usually does not mean health hazard.
- If irritation or allergy occurs, obtain medical help.

### **EYE CONTACT:**

Measures:

- In case of contact with eyes flush with low-pressure water holding eyelids apart (for at least 15 minutes).
- If irritation persists, obtain medical help.

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

In case of contact with skin, irritation and allergy rarely occur.

#### <u>Indication of any immediate medical attention and special treatment needed:</u> 4.3.

Note to the physician: The physician should be told that the product itself does not cause allergy or irritation, only a small number of people with special physical condition can develop allergies or irritation to burn gel.

# **SECTION 5: FIREFIGHTING MEASURES**

#### **Extinguishing media:** 5.1.

#### Suitable extinguishing media: 5.1.1.

Dry powder, foam, carbon dioxide and water mist.

#### Unsuitable extinguishing media: 5.1.2.

No unsuitable extinguishing media known.

#### Special hazards arising from the substance or mixture: 5.2.

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.

#### Advice for firefighters: 5.3.

Wear full protective clothing and self-contained breathing apparatus.

<sup>\*\*:</sup> Substance having occupational exposure limit value.



### **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:

Contain and store leaks without mixing them with other products.

#### **Environmental precautions:** 6.2.

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.

#### Methods and material for containment and cleaning up: 6.3.

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

Dispose of the collected waste in accordance with applicable regulations.

#### 6.4. Reference to other sections:

For further and detailed information see Sections 8 and 13.

### **SECTION 7: HANDLING AND STORAGE**

#### Precautions for safe handling: 7.1.

Observe conventional hygiene precautions.

Read the product instructions carefully before use to avoid incorrect use of the product.

### Technical measures:

No special measures required.

# Precautions against fire and explosion:

No special measures required.

#### Conditions for safe storage, including any incompatibilities: 7.2.

# Technical measures and storage condition:

Humidity: ≤80 %.

Store in a well-ventilated room without corrosive gases.

Keep away from open fire, strong alkalis, strong acids, strong oxidants.

Storage temperature: ≥o - ≤40 °C. Incompatible materials: See Section 10.5 Packaging material: No special prescriptions.

Specific end use(s): 7.3.

No specific instructions available.

### SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

#### 8.1. Control parameters:

Occupational exposure limit values (EH40/2005 Workplace exposure limits):

Propane-1,2-diol (CAS: 57-55-6):

total vapour and particulates: Long-term exposure limit (8-hr TWA reference period): 150 ppm; 474 mg/m<sup>3</sup>

particulates: Long-term exposure limit (8-hr TWA reference period): 10 mg/m<sup>3</sup>

Glycerol, mist (CAS: 56-81-5):

Long-term exposure limit (8-hr TWA reference period): 10 mg/m<sup>3</sup>

DNEL values		Oral exposure		Dermal exposure		Inhalative exposure	
		Short term	Long term	Short term	Long term	Short term	Long term
		(acute)	(chronic)	(acute)	(chronic)	(acute)	(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

Date of issue: 10. 07. 2020

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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

#### 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.

#### Individual protection measures, such as personal protective equipment: 8.2.2.

Observe personal hygiene requirements and ensure regular physical examination.

- Eye/face protection: Use appropriate protective glasses (EN 166).
- Skin protection:
  - Hand protection: Use appropriate protective gloves (EN 374). a.
  - Other: Use appropriate protective clothing.
- **Respiratory protection:** Use appropriate respiratory protective device.
- Thermal hazards: No thermal hazards known.

#### Environmental exposure controls: 8.2.3.

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:	white or yellowish, clear, homogeneous liquid
2.	Odour:	no data*
3.	Odour threshold:	no data*
4.	pH:	5.0 – 7.5
5.	Melting point/freezing point:	no data*
6.	Initial boiling point and boiling range:	no data*
7.	Flash point:	no data*
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):	water soluble
15.	Partition coefficient: n-octanol/water:	no data*
16.	Auto-ignition temperature:	no data*
17.	Decomposition temperature:	no data*
18.	Viscosity:	5000 – 30,000 mPa.s (25 ± 2 °C)
19.	Explosive properties:	no data*
20.	Oxidizing properties:	no data*

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#### Other information: 9.2.

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**

Reactivity: 10.1.

No reactivity known.

Chemical stability: 10.2.

Stable under normal conditions.

Possibility of hazardous reactions: 10.3.

No hazardous reactions known.

Conditions to avoid: 10.4.

Avoid high temperature and high humidity.

**Incompatible materials:** 10.5.

No incompatible materials known.

**Hazardous decomposition products:** 10.6.

No hazardous decomposition products known.

### **SECTION 11: TOXICOLOGICAL INFORMATION**

#### 11.1. <u>Information on toxicological effects:</u>

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.

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

No data available.

Relevant toxicological properties: 11.1.2.

No data available.

Information on likely routes of exposure: 11.1.3.

Ingestion, inhalation, skin contact, eye contact.

Symptoms related to the physical, chemical and toxicological characteristics:

No data available.

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

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

Interactive effects: 11.1.6.

No data available.

Absence of specific data: 11.1.7.

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.

Persistence and degradability: 12.2.

No data available.

**Bioaccumulation potential:** 12.3.

No data available.

Mobility in soil: 12.4.

No data available.



#### Results of PBT and vPvB assessment: 12.5.

No data available.

#### Other adverse effects: 12.6.

No data available.

# SECTION 13: DISPOSAL CONSIDERATIONS

#### Waste treatment methods: 13.1.

Disposal according to the local regulations.

### Information regarding the disposal of the product:

Dispose of in accordance with applicable regulations.

The product is not considered as hazardous waste.

If the product has been used, it should be treated as medical device waste.

### 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.

#### Information regarding the disposal of the packaging: 13.1.2.

Dispose of in accordance with applicable regulations.

### Physical/chemical properties that may affect waste treatment options shall be specified:

No data available.

#### Sewage disposal: 13.1.4.

No data available.

#### Special precautions for any recommended waste treatment: 13.1.5.

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.

#### **UN proper shipping name:** 14.2.

No proper shipping name.

#### Transport hazard class(es): 14.3.

No transport hazard classes.

#### Packing group: 14.4.

No packing group.

#### **Environmental hazards:** 14.5.

Marine pollutant: No.

#### 14.6. Special precautions for user:

Take measures to prevent open fire, high temperature, rain and sunshine during product transportation.

#### Transport in bulk according to Annex II of MARPOL and the IBC Code: 14.7.

Not applicable.

# **SECTION 15: REGULATORY INFORMATION**

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

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)

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

# **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 (September 2019, 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.

Date of issue: 10. 07. 2020

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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

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.

Professional help regarding the explanation of the safety data sheet:

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