

Platsil® Prosthetic Adhesive

Safety Datasheet

According to regulation (EC) n° 1907/2006 Annex II

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

1.1 Product identifier

Commercial product name: Platsil® Prosthetic Adhesive

Product identifier: Hexamethyldisiloxane

CAS No.: 107-46-0

EC-No.: 203-492-7

REACH registration number: 01-2119496108-31-0002

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

Use of substance / preparation:

Industrial.
cosmetics

For this product, uses according to REACH have been identified. To provide a better readability, more specific information on uses is given in section 16.

1.3 Details of the supplier of the safety data sheet

Manufacturer/distributor: Neill's Materials
Unit 5 Chapel Pond Hill
Bury St Edmunds, Suffolk
IP32 7HT, United Kingdom

Information about the Safety Data Sheet: info@neillsmaterials.co.uk
www.neillsmaterials.co.uk

1.4 Emergency telephone number

+44 (0) 1284 630028

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

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

Hazard class	Hazard category	Route of exposure	H-Code
Flammable liquids	Category 2		H225
Acute aquatic toxicity	Category 1		H400
Chronic aquatic toxicity	Category 2		H411

2.2 Label elements

Labelling according to Regulation (EC) No. 1272/2008:

Pictogram(s):



Signal Word: Danger

H-Code	Hazard Statements
H225	Highly flammable liquid and vapour.
H400	Very toxic to aquatic life.
H411	Toxic to aquatic life with long lasting effects.

P-Code	Precautionary Statements
P210	Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
P243	Take action to prevent static discharges.
P273	Avoid release to the environment.
P391	Collect spillage.
P403+P235	Store in a well-ventilated place. Keep cool.

Hazard ingredients (labelling):

Hexamethyldisiloxane

EC-No.: 203-492-7

2.3 Other hazards

No data available.

SECTION 3: Composition/information on ingredients

3.1 Substances

3.1.1 Chemical characteristics

CAS No.: 107-46-0

Hexamethyldisiloxane

3.1.2 Hazardous ingredients

Type	CAS No.	EC-No. REACH no.	Material	Content %	Classification according to Regulation (EC) No. 1272/2008*	Comment
INHA	107-46-0	203-492-7 01-2119496108-31	Hexamethyldisiloxane	<=100	Flam. Liq. 2; H225 Aquatic Acute 1; H400 Aquatic Chronic 2; H411	[1] Ma = 1

Type: INHA: ingredient, VERU: impurity

[1] = Hazardous or environmentally harmful substance; [2] = substance with a Community workplace exposure limit; [3] = PBT substance; [4] = vPvB substance

Ma = M-factor for acute aquatic toxicity

Mc = M-factor for chronic aquatic toxicity

*Classification codes are explained in section 16.

3.2 Mixtures

not applicable

SECTION 4: First aid measures

4.1 Description of first aid measures

General information:

In case of accident or if you feel unwell seek medical advice (show label or SDS where possible).

After contact with the eyes:

Rinse immediately with plenty of water. Seek medical advice in case of continuous irritation.

After contact with the skin:

Wash with plenty of water or water and soap. In the event of a visible skin change or other complaints, seek medical advice (show label or SDS where possible).

After inhalation:

Provide fresh air.

After swallowing:

Give several small portions of water to drink. Do not induce vomiting.

4.2 Most important symptoms and effects, both acute and delayed

Any relevant information can be found in other parts of this section.

4.3 Indication of any immediate medical attention and special treatment needed

Further toxicology information in section 11 must be observed.

SECTION 5: Firefighting measures**5.1 Extinguishing media****Suitable extinguishing media:**

extinguishing powder, sand, alcohol-resistant foam, carbon dioxide.

Extinguishing media which must not be used for safety reasons:

water jet, water spray.

5.2 Special hazards arising from the substance or mixture

no data available

5.3 Advice for firefighters**Special protective equipment for fire fighting:**

Use respiratory protection independent of recirculated air.

SECTION 6: Accidental release measures**6.1 Personal precautions, protective equipment and emergency procedures**

Wear personal protection equipment (see section 8).

6.2 Environmental precautions

Prevent material from entering sewers or surface waters. Contain any fluid that runs out using suitable material (e.g. earth).

6.3 Methods and material for containment and cleaning up

Absorb with a liquid binding material such as diatomaceous earth and dispose of according to local/state/federal regulations. Do not flush away with water. Collect into sealed containers.

Further information:

Eliminate all sources of ignition.

6.4 Reference to other sections

Relevant information in other sections has to be considered. This applies in particular for information given on personal protective equipment (section 8) and on disposal (section 13).

SECTION 7: Handling and storage**7.1 Precautions for safe handling****Precautions for safe handling:**

Ensure adequate ventilation. Must be syphoned off in situ.

Precautions against fire and explosion:

Keep away from heat, sparks and flame. Keep away from sources of ignition and do not smoke. Do not weld, cut, or grind on empty containers. Take precautionary measures against electrostatic charging. Flammable vapors may accumulate and form explosive mixtures with air in containers, process vessels, including partial, empty and uncleaned containers and vessels, or other enclosed spaces. Cool endangered containers with water.

7.2 Conditions for safe storage, including any incompatibilities**Conditions for storage rooms and vessels:**

Store in a cool place.

Advice for storage of incompatible materials:

none known

Further information for storage:

Store cool. Keep container tightly closed.

Maximum temperature allowed during storage and transportation: 40 °C

7.3 Specific end use(s)

No data available.

If the annex to this safety data sheet contains exposure scenarios for end uses, the information provided therein has to be observed.

SECTION 8: Exposure controls/personal protection
8.1 Control parameters
Maximum airborne concentrations at the workplace:

CAS No.	Material	Type	mg/m ³	ppm	Dust fract.	Fibre/m ³
	Aerosol - inhalable fraction		10,0			

The aerosol limit specified is a recommendation should aerosol be formed during processing.

Derived No-Effect Level (DNEL):
Hexamethyldisiloxane

Area of use:	Value:
Worker; dermal; systemic (acute) systemic (long term)	126 mg/kg/day
Worker; by inhalation; systemic (acute) systemic (long term)	890 mg/m ³ 134 ppm
Consumer; dermal; systemic (acute) systemic (long term)	25 mg/kg/day
Consumer; by inhalation; systemic (acute) systemic (long term)	266 mg/m ³ 40 ppm
Consumer; oral; systemic (long term)	25 mg/kg/day

Predicted No Effect Concentration (PNEC):
Hexamethyldisiloxane

Area of use:	Value:
freshwater	0,008 mg/l
marine water	0,0008 mg/l
Intermittent release	0,05 mg/l
Sediment (freshwater)	0,065 mg/kg wet weight
Sediment (marine water)	0,0065 mg/kg wet weight
Soil	0,25 mg/kg wet weight
sewage treatment plant	10 mg/l
Secondary poisoning	67 mg/kg food

8.2 Exposure controls
8.2.1 Exposure in the work place limited and controlled
General protection and hygiene measures:

Do not eat, drink or smoke when handling. Do not breathe vapours.

Personal protection equipment:
Respiratory protection

In accordance with instructions: not required . Use respiratory protection where there is insufficient ventilation. gas mask filter ABEK .

Eye protection

Recommendation: protective goggles .

Hand protection

Recommendation: Protective gloves made of butyl rubber. Gloves suitable for up to 60 minutes' use. The selection of appropriate gloves not only depends on the material, but also on other quality characteristics, and may vary depending on the manufacturer. Please observe information from your glove supplier in terms of permeability and breakthrough time.

8.2.2 Exposure to the environment limited and controlled

Prevent material from entering surface waters and soil.

8.3 Further information for system design and engineering measures

Observe information in section 7. Observe regulations for protection against explosion.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Property:	Value:	Method:
Appearance		
Physical state / form.....	liquid	
Colour.....	colourless, clear	
Odour		
Odour.....	faint	
Odour limit		
Odour limit.....	no data available	
pH-Value		
pH-Value.....	not applicable	
Melting point/freezing point		
Melting point / melting range.....	-68 °C	
Initial boiling point and boiling range		
Boiling point / boiling range.....	100 °C at 1013 hPa	
Flash point		
Flash point.....	-6 °C	(DIN 51755)
Evaporation rate		
Evaporation rate.....	no data available	
Upper/lower flammability or explosive limits		
Lower explosion limit (LEL).....	0,68 Vol-%	(Lit.)
Upper explosion limit (UEL).....	26 Vol-%	(Lit.)
Vapour pressure		
Vapour pressure.....	175 hPa / 50 °C	
Vapour pressure.....	44 hPa / 20 °C	
Solubility(ies)		
Water solubility / miscibility.....	virtually insoluble; < 0,001 g/l at 20 °C	
Vapour density		
Relative gas/vapour density.....	No data known.	
Relative Density		
Relative Density.....	approx. 0,76 (25 °C)	(DIN 51757)
	(Water / 4 °C = 1,00)	
Density.....	approx. 0,76 g/cm³ (25 °C)	(DIN 51757)
Partition coefficient: n-octanol/water		
Partition coefficient: n-octanol/water.....	> 4 at 25 °C (log P_{ow})	(Lit.)
Auto-ignition temperature		
Ignition temperature.....	340 °C	(DIN 51794)
Decomposition temperature		
Thermal decomposition.....	No decomposition when used according to regulations.	
Viscosity		
Viscosity (dynamic).....	0,5 mPa.s at 25 °C	(DIN 51562)
Viscosity (kinematic).....	approx. 0,65 mm²/s at 25 °C	(DIN 53018)
Explosive properties		
Explosion group.....	II B	

Molecular mass

Molecular mass: no data available

9.2 Other information

pH Value: Product displays neutral reaction.

SECTION 10: Stability and reactivity
10.1 – 10.3 Reactivity; Chemical stability; Possibility of hazardous reactions

If stored and handled in accordance with standard industrial practices no hazardous reactions are known.

Relevant information can possibly be found in other parts of this section.

10.4 Conditions to avoid

none known

10.5 Incompatible materials

none known

10.6 Hazardous decomposition products

If stored and handled properly: none known .

SECTION 11: Toxicological information
11.1 Information on toxicological effects
11.1.1 Acute toxicity
Assessment:

Based on the available data acute toxic effects are not expected after single oral exposure. Based on the available data acute toxic effects are not expected after single dermal exposure. Based on the available data acute toxic effects are not expected after short-term inhalative exposure.

Product details:

Route of exposure	Result/Effect	Species/Test system	Source
oral	LD ₅₀ : > 16 mL/kg	rat	test report
dermal	LD ₅₀ : > 2000 mg/kg Neither mortality nor clinical signs of toxicity were observed with the given dose.	rabbit	test report OECD 402
by inhalation (vapour)	LC ₅₀ : 106 mg/l = 16000 ppm; 4 h	rat	test report OECD 403

11.1.2 Skin corrosion/irritation
Assessment:

Based on the available data a clinically relevant skin irritation hazard is not expected.

Product details:

Result/Effect	Species/Test system	Source
not irritating	rabbit	test report OECD 404

11.1.3 Serious eye damage / eye irritation
Assessment:

Based on the available data a clinically relevant eye irritation hazard is not expected.

Product details:

Result/Effect	Species/Test system	Source
not irritating	rabbit	test report OECD 405

11.1.4 Respiratory or skin sensitization
Assessment:

Based on the available data a sensitization reaction is not expected from this product.

Product details:

Route of exposure	Result/Effect	Species/Test system	Source
dermal	not sensitizing	Voluntary persons; Human skin patch test	test report

11.1.5 Germ cell mutagenicity
Assessment:

Based on known data a significant mutagenic potential may be excluded.

Product details:

Result/Effect	Species/Test system	Source
negative	mutation assay (in vitro) bacterial cells	test report OECD 471
negative	mutation assay (in vitro) mammalian cells	test report OECD 476
negative	chromosome aberration assay (in vitro) mammalian cells	test report OECD 473
negative	chromosome aberration assay (in vivo) rat (Sprague Dawley) intraperitoneal; bone marrow cells	test report OECD 475

11.1.6 Carcinogenicity
Assessment:

Animal tests have not revealed any carcinogenic effects.

Product details:

Result/Effect	Species/Test system	Source
NOAEC: $\geq 33,2$ mg/l NOAEC = NOAEC (carcinogenic effects relevant for humans)	carcinogenicity study rat (F344) by inhalation (vapour) 2 a; 5 d/w; 6 hours/day	test report OECD 453

11.1.7 Reproductive toxicity
Assessment:

Animal tests have shown no indications of possibility of damage to embryo and impairment of fertility.

Product details:

Result/Effect (Examinations of fertility disruption)	Species/Test system	Source
NOAEC: $\geq 33,2$ mg/l NOAEC = NOAEC (fertility)	two generation study rat (Sprague Dawley) by inhalation (vapour) ; 7 d/w; 6 hours/day	test report EPA OPPTS 870.3800+870.6300

Result/Effect (Examinations of developmental toxicity and teratogenicity)	Species/Test system	Source
NOAEC (developmental): 10,6 mg/l NOAEC (maternal): >= 33,2 mg/l Symptoms/Effect: Pups: lack of habituation	Reproduction and Fertility Effects + Developmental Neurotoxicity Study rat (Sprague Dawley) by inhalation (vapour) ; 7 d/w; 6 hours/day	test report EPA OPPTS 870.3800+870.6300

11.1.8 Specific target organ toxicity (single exposure)

Assessment:
For this endpoint no toxicological test data is available for the whole product.

11.1.9 Specific target organ toxicity (repeated exposure)

Assessment:
In animal experiments with repeated exposure no effects with relevance for humans were observed.

Product details:

Result/Effect	Species/Test system	Source
NOAEL: >= 1000 mg/kg NOAEL = NOAEL (relevant to humans)	Subacute study rat oral (gavage) 28 d	test report OECD 407
NOAEL: >= 1000 mg/kg NOAEL = NOAEL (relevant to humans)	Subacute study rat dermal 28 d; 5 d/w; 6 hours/day	test report OECD 410
NOAEC: > 33,2 mg/l NOAEC = NOAEC (relevant to humans)	chronic study rat 2 a; 5 d/w; 6 hours/day	test report OECD 453

11.1.10 Aspiration hazard

Assessment:
For this endpoint no toxicological test data is available for the whole product.

11.1.11 Further toxicological information

May cause skin irritation at prolonged/repeated contact with the product.

SECTION 12: Ecological information

12.1 Toxicity

Assessment:
Very toxic to aquatic organisms. Toxic to aquatic life with long lasting effects.

Product details:

Result/Effect	Species/Test system	Source
LC ₅₀ : 0,46 mg/l (measured)	dynamic rainbow trout (Oncorhynchus mykiss) (96 h)	test report OECD 203
EC ₅₀ : > 0,37 mg/l (measured)	static Daphnia magna (48 h)	test report OECD 202
IC ₁₀ (growth rate): 0,14 mg/l (measured)	static Selenastrum capricornutum (95 h)	test report OECD 201
IC ₅₀ (growth rate): > 0,55 mg/l (measured)	static Selenastrum capricornutum (95 h)	test report OECD 201
EC ₅₀ (respiratory inhibition): >= 100 mg/l (nominal)	static sludge (3 h)	test report OECD 209

NOEC: >= 0,04 mg/l (measured)	dynamic carp (Cyprinus carpio) (56 d)	test report OECD 305
NOEC (reproduction): 0,08 mg/l (measured)	semistatic Daphnia magna (21 d)	test report OECD 211

12.2 Persistence and degradability

Assessment:

The substance is degradable in abiotic processes.

Product details:

Biodegradation:

Result	Test system/Method	Source
2 % / 28 d Not readily biodegradable.	biological oxygen demand (BOD)	test report OECD 301C

Hydrolysis:

Result	Test system	Source
Half-life: 1,47 h	pH 5; 24,8 °C	test report OECD 111
Half-life: 120 h	pH 7; 24,7 °C	test report OECD 111
Half-life: 12,4 h	pH 9; 24,8 °C	test report OECD 111

12.3 Bioaccumulative potential

Assessment:

Under experimental conditions the substance showed an increased potential for bioaccumulation.

Product details:

Result/Effect	Species/Test system	Source
Bioconcentration factor (BCF): 1290 - 2410	carp (Cyprinus carpio) (70 d; 0,04 mg/l)	no data available
Bioconcentration factor (BCF): 776 - 1660	carp (Cyprinus carpio) (70 d; 0,004 mg/l)	no data available

12.4 Mobility in soil

Assessment:

The partition coefficient soil/water (logK_{oc}) indicates a medium mobility in soil.

Product details:

adsorption - desorption:

Result	Test system/Method	Source
log K _{OC} : 2,53	Berechnung	no data available

12.5 Results of PBT and vPvB assessment

This product contains no relevant substances considered to be persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB).

12.6 Other adverse effects

none known

SECTION 13: Disposal considerations

13.1 Waste treatment methods

13.1.1 Material

Recommendation:

Dispose of according to regulations by incineration in a special waste incinerator. Observe local/state/federal regulations.

13.1.2 Uncleaned packaging

Recommendation:

Completely discharge containers (no tear drops, no powder rest, scraped carefully). Containers may be recycled or re-used.
Observe local/state/federal regulations.

13.1.3 Waste Disposal Legislation Ref.No.(EC)

It is not possible to determine a waste code for this product in accordance with the European Waste Catalogue (EWC) since it is only possible to classify it according to how it is used by the customer. The waste code is to be determined within the EU in liaison with the waste-disposal operator.

SECTION 14: Transport information**14.1 – 14.4 UN number; UN proper shipping name; Transport hazard class(es); Packing group****Road ADR:**

Valuation: Dangerous Goods
14.1 UN no.: 1993
14.2 Proper Shipping Name: Entzündbarer flüssiger Stoff, n.a.g. (Hexamethyldisiloxan)
14.2 Proper Shipping Name (national)....: Flammable liquid, n.o.s (Hexamethyldisiloxane)
14.3 Class: 3
14.4 Packaging Group: II

Railway RID:

Valuation: Dangerous Goods
14.1 UN no.: 1993
14.2 Proper Shipping Name: Entzündbarer flüssiger Stoff, n.a.g. (Hexamethyldisiloxan)
14.2 Proper Shipping Name (national)....: Flammable liquid, n.o.s (Hexamethyldisiloxane)
14.3 Class: 3
14.4 Packaging Group: II

Transport by sea IMDG-Code:

Valuation: Dangerous Goods
14.1 UN no.: 1993
14.2 Proper Shipping Name: Flammable liquid, n.o.s. (Hexamethyldisiloxane)
14.3 Class: 3
14.4 Packaging Group: II

Air transport ICAO-TI/IATA-DGR:

Valuation: Dangerous Goods
14.1 UN no.: 1993
14.2 Proper Shipping Name: Flammable liquid, n.o.s. (Hexamethyldisiloxane)
14.3 Class: 3
14.4 Packaging Group: II

14.5 Environmental hazards

Hazardous to the environment: yes
Marine Pollutant (IMDG): yes

14.6 Special precautions for user

Relevant information in other sections has to be considered.

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

Bulk transport in tankers is not intended.

SECTION 15: Regulatory information**15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**

National and local regulations must be observed.

For information on labelling please refer to section 2 of this document.

Directive 2012/18/EU of the European Parliament and of the Council on the control of major-accident hazards involving dangerous substances (Seveso III):

Listed in Directive	Ser. number in list	Qualifying Quantity 1	Qualifying Quantity 2
FLAMMABLE LIQUIDS	P5c	5.000 t	50.000 t
ENVIRONMENTAL HAZARDS	E1	100 t	200 t

Relevant regulations:

SI 2002/1689: CHIP Regulations 2002

SI 2002/2677: COSHH Regulations 2002

SI 1999/3242: Management of Health & Safety at Work Regulations 1999

Health & Safety at Work Act 1974

SI 1993/1643: Environmental Protection Act 1993 & Subsidiary Regulations.

Other national and local measures relating to the workplace, pollution control, environmental protection and waste control.

Other specifications, restrictions and prohibitions:

Regulation (EC) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals: Not applicable

15.2 Chemical safety assessment

For this product, a chemical safety assessment according to (EC) regulation 1907/2006 (REACH) has been carried out.

15.3 Details of international registration status

Relevant information about individual substance inventories, where available, is given below.

South Korea (Republic of Korea).....	ECL (Existing Chemicals List): This product is listed in, or complies with, the substance inventory.
Japan.....	ENCS (Handbook of Existing and New Chemical Substances): This product is listed in, or complies with, the substance inventory.
Australia	AICS (Australian Inventory of Chemical Substances): This product is listed in, or complies with, the substance inventory.
People's Republic of China.....	IECSC (Inventory of Existing Chemical Substances in China): This product is listed in, or complies with, the substance inventory.
Canada.....	DSL (Domestic Substance List): This product is listed in, or complies with, the substance inventory.
Philippines	PICCS (Philippine Inventory of Chemicals and Chemical Substances): This product is listed in, or complies with, the substance inventory.
United States of America (USA).....	TSCA (Toxic Substance Control Act Chemical Substance Inventory): All components of this product are listed as active or are in compliance with the substance inventory.
Taiwan (Republic of China)	TCSI (Taiwan Chemical Substance Inventory): This product is listed in, or complies with, the substance inventory. General note: The Taiwanese chemicals regulation requires a phase 1 registration for TCSI-listed or TCSI-compliant substances if imports to Taiwan or manufacturing in Taiwan exceed the trigger quantity of 100 kg/a (for mixtures to be calculated per each ingredient). It is the duty of the importing/manufacturing legal entity to take care of this obligation.
European Economic Area (EEA)	REACH (Regulation (EC) No 1907/2006): General note: the registration obligations for substances imported into the EEA or manufactured within the EEA by the supplier mentioned in section 1 are fulfilled by the said supplier. The registration obligations for substances imported into the EEA by customers or other downstream users must be fulfilled by the latter.

SECTION 16: Other information

16.1 Material

The details in this document are based on the state of our knowledge at the time of revision. They do not constitute an assurance of the described product properties in terms of statutory warranty requirements.

The providing of this document to a recipient does not relieve the recipient of his or her responsibility toward compliance with all laws and stipulations applicable to the product. This applies in particular to the further sale or distribution of the product or substances or items containing the product, in other jurisdictions and with regard to the protection of third-party intellectual property rights. If the described product is processed or mixed with other substances or materials, the details stated in this document cannot be conferred to the resultant new product unless this has been expressly mentioned. If the product is repackaged, the recipient is obligated to additionally provide the required safety-related information.

16.2 Identified uses (REACH)

General information:

Please send requests for additional uses or for extension of exposure scenarios to the following e-mail address:

info@neillsmaterials.co.uk

All identified uses have been summarized tabularly. The uses are linked to the subsequently described exposure scenarios by the sequential exposure scenario number given in the table.

Identified uses with exposure scenarios:

Conditions for safe use, and - if applicable - a more detailed specification of the categories, can be found in related the exposure scenarios (ES) which are indicated in the right column.

Please note: Exposure scenarios usually are based only on single registered substances and their uses. Mixtures might contain other hazardous substances which require additional measures.

Formulation of personal care products; industrial	ES No.
SU 3 – ERC2 – PROC1, PROC2, PROC3, PROC5, PROC8a, PROC8b, PROC9 – SU 10 – PC39	1

16.3 Further information:

Commas appearing in numerical data denote a decimal point. Vertical lines in the left-hand margin indicate changes compared with the previous version. This version supersedes all previous versions.

Explanation of the GHS classification code:

Flam. Liq. 2; H225 : Flammable liquids Category 2; Highly flammable liquid and vapour.

Aquatic Acute 1; H400: Acute aquatic toxicity Category 1; Very toxic to aquatic life.

Aquatic Chronic 2; H411 Chronic aquatic toxicity Category 2; Toxic to aquatic life with long lasting effects.

..... :

This safety data sheet contains an annex on the following pages. (Annex to the Safety Data Sheet According to Article 31(7) of Regulation 1907/2006/EC (REACH))

ES1	Formulation of personal care products; industrial
------------	--

1. Processes and activities covered by this description

PROC5 is considered as a worst-case for formulation processes, so the other PROCs of these processes are not quantified.

Relevant use descriptors for this scenario:

SU 3: Industrial uses: Uses of substances as such or in preparations at industrial sites

ERC2: Formulation of preparations

PROC1: Use in closed process, no likelihood of exposure; **PROC2:** Use in closed, continuous process with occasional controlled exposure; **PROC3:** Use in closed batch process (synthesis or formulation); **PROC5:** Mixing or blending in batch processes for formulation of preparations and articles (multistage and/ or significant contact); **PROC8a:** Transfer of substance or preparation (charging/ discharging) from/ to vessels/ large containers at non-dedicated facilities; **PROC8b:** Transfer of substance or preparation (charging/ discharging) from/ to vessels/ large containers at dedicated facilities; **PROC9:** Transfer of substance or preparation into small containers (dedicated filling line, including weighing)

SU 10: Formulation [mixing] of preparations and/ or re-packaging (excluding alloys)

PC39: Cosmetics, personal care products

Concentration of substance in preparation/mixture or article:

The exposure scenario is based on the following ingredients:
Hexamethyldisiloxane

Relevant substance concentrations are given in the contributing scenarios. Unless otherwise stated, values in the exposure scenarios are related to the following substances, and not to the complete product.

2. Exposure scenarios

2.1 Contributing scenario controlling environmental exposure:

ERC2

Concentration of substance in preparation/mixture or article:

<=100% Hexamethyldisiloxane

Amounts used:

Annual amount per site : 20 t

Environment factors not influenced by risk management:

Receiving Surface Water (Flow Rate): 18.000 m³/day

Dilution factor (river)..... : 10

Dilution factor (coastal areas) : 100

Other given operational conditions affecting environmental exposure:

Emission days per year..... : 200

Emission or release factor : 0,02 % (Air)

Emission or release factor : 0,09 % (Water)

Risk management measures related to the environment:

Air : scrubbers ; Condenser ; incineration

Conditions and measures related to sewage treatment plant:

STP type : default-sized municipal WWTP

STP effluent..... : 2.000 m³/day

Sludge treatment..... : Recovery for agriculture or horticulture can not be excluded.

Conditions and measures related to external treatment of waste for disposal:

Solid wastes are ultimately disposed of via landfill or incineration.

2.2 Contributing scenario controlling worker exposure:

PROC5



Concentration of substance in preparation/mixture or article:

<=100% Hexamethyldisiloxane

Physical state during application:

liquid

Vapour pressure : 6375 Pa

Amounts used:

Not of relevance.

Duration and frequency of use:

Exposure time : 15 - 60 min; per day

Risk management measures related to human health (worker):

Local exhaust ventilation plus good work practice required. (Effectiveness: 90 %)

Goggles/face shield is required where full face respirator is not worn.

**2.3 Contributing scenario controlling worker exposure:
PROC8a**

Concentration of substance in preparation/mixture or article:

<=100% Hexamethyldisiloxane

Physical state during application:

liquid

Vapour pressure : 6375 Pa

Amounts used:

Not of relevance.

Duration and frequency of use:

Exposure time : > 4 h; per day

Risk management measures related to human health (worker):

Local exhaust ventilation plus good work practice required. (Effectiveness: 90 %)

Goggles/face shield is required where full face respirator is not worn.

**2.4 Contributing scenario controlling worker exposure:
PROC8b**

Concentration of substance in preparation/mixture or article:

<=100% Hexamethyldisiloxane

Physical state during application:

liquid

Vapour pressure : 6375 Pa

Amounts used:

Not of relevance.

Duration and frequency of use:

Exposure time : > 4 h; per day

Risk management measures related to human health (worker):

Local exhaust ventilation required. (Effectiveness: 97 %)

Goggles/face shield is required where full face respirator is not worn.

2.5 Contributing scenario controlling worker exposure: PROC9

Concentration of substance in preparation/mixture or article:

<=10% Hexamethyldisiloxane

Physical state during application:

liquid

Vapour pressure : 6375 Pa

Amounts used:

Not of relevance.

Duration and frequency of use:

Exposure time : > 4 h; per day

Risk management measures related to human health (worker):

Local exhaust ventilation plus good work practice required. (Effectiveness: 90 %)

Goggles/face shield is required where full face respirator is not worn.

3. Exposure estimation and reference to its source

DNEL and PNEC values of relevant ingredients are given in section 8 of the main part of this document.

Small numeric values in the scenario may be rounded for technical reasons.

Unless otherwise specified in the scenario, default parameters of the methods and conditions have been used.

For each type of exposure usually only the most critical value is given, without differentiation between, e.g., short term and long term exposure.

For a complete exposure estimation, the values for different routes of exposure and activities may have to be summed up.

RCR = Risk Characterization Ratio

Exposure type	Specific conditions	Level of exposure	RCR	Method
freshwater	-	0,00022 mg/l	0,028	EUSES 2.1.1
marine water	-	0,00045 mg/l	0,56	EUSES 2.1.1
Sediment (freshwater)	-	0,0018 mg/kg wet weight	0,28	EUSES 2.1.1
	A factor of 10 was applied to the RCR.			
Sediment (marine water)	-	0,0037 mg/kg wet weight	5,7	EUSES 2.1.1
	A factor of 10 was applied to the RCR. Applying waste water treatment as risk management measure would give an RCR similar to the fresh water value.			
Soil	-	0,0010 mg/kg wet weight	0,040	EUSES 2.1.1
	A factor of 10 was applied to the RCR.			
sewage treatment plant	-	0,0022 mg/l	0,00022	EUSES 2.1.1
dermal, long-term	PROC 5.	0,07 mg/kg/day	0,00055	ECETOC TRA v2.0
inhalative, long-term	PROC 5.	6,6 mg/m³	0,0074	ECETOC TRA v2.0
dermal, long-term	PROC 8a.	0,14 mg/kg/day	0,0011	ECETOC TRA v2.0
inhalative, long-term	PROC 8a.	33 mg/m³	0,037	ECETOC TRA v2.0
dermal, long-term	PROC 8b.	0,69 mg/kg/day	0,0055	ECETOC TRA v2.0
inhalative, long-term	PROC 8b.	10 mg/m³	0,011	ECETOC TRA v2.0
dermal, long-term	PROC 9.	0,07 mg/kg/day	0,00055	ECETOC TRA v2.0
inhalative, long-term	PROC 9.	20 mg/m³	0,022	ECETOC TRA v2.0

4. Evaluation guidance to downstream user

no data available .



Polytek
Development Corp.

NEILL'S
MATERIALS
A Division of Polytek® Development Corp.

Platsil® Prosthetic Adhesive | Safety Datasheet | Page 16

SAFETY: Before use, thoroughly read Safety Data Sheets and product labels. Follow safety precautions and directions.

Unless specified to the contrary, the values given have been established on standardized test specimens at room temperature. The figures should be regarded as guide values only and not as binding minimum values. Kindly note that the results refer exclusively to the specimens tested. Under certain conditions, the test results established can be affected to a considerable extent by the processing conditions and manufacturing process.

DISCLAIMER: The information in this bulletin and otherwise provided by Polytek® Development Corp. is considered accurate. However, no warranty is expressed or implied regarding the accuracy of the data, the results to be obtained by the use thereof, or that any such use will not infringe any patent. Before using, the user shall determine the suitability of the product for the intended use and user assumes all risk and liability whatsoever in connection therewith.