

Safety Data Sheet

According to Regulation (EC) N° 1907/2006 modified by regulation (EU) N° 453/2010

Trade name: Atos # 8011 Provox Skin Barrier (50 pcs)

Product. No: # 8011

Version: 1.0 / EN

Print date: 11/4/15

Specification No: 1.0

Page 1 of 25

Revision date: November/03/2015

1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1. Product identifier:

1.1.2 Trade name / designations

8011 Provox Skin Barrier (50 pcs)

1.1.3 Other means of identification:

n/a

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

TRANSPORT CLASSIFICATION WITH RULES OF EXEMPTION. SEE CHAPTER 14.

1.2.1 Relevant identified uses

Wet Wipe –Skin Barrier

1.2.2. Uses advised against:

Use only as directed in the original product packaging.

See chapter 16 for a general overview

1.3 Details of the supplier of the safety data sheet:

Supplier (manufacturer/importer/only representative/downstream user/distributor):

Atos Medical AB

Kraftgatan 8

242 35 Hörby

SE-24222, Hörby

SWEDEN

E-Mail (competent person):

n/a

Information contact:

Telephone +46 415 19800

Fax +46 415 19898

Safety Data Sheet

According to Regulation (EC) N° 1907/2006 modified by regulation (EU) N° 453/2010

Trade name: Atos # 8011 Provox Skin Barrier (50 pcs)

Product. No: # 8011

Version: 1.0 / EN

Print date: 11/4/15

Specification No: 1.0

Page 2 of 25

Revision date: November/03/2015

1.4 EMERGENCY TELEPHONE NUMBER:

EUROPE: 112 European emergency phone number, available everywhere in the EU

SWEDEN: Giftinformationscentralen / Poison Information Centre

Telephone 112 Poison Information (24 h)

Telephone 08 331231 Other questions concerning acute poisonings (9am–5pm, monday–friday)

Safety Data Sheet

According to Regulation (EC) N° 1907/2006 modified by regulation (EU) N° 453/2010

Trade name: Atos # 8011 Provox Skin Barrier (50 pcs)

Product. No: # 8011

Version: 1.0 / EN

Print date: 11/4/15

Specification No: 1.0

Page 3 of 25

Revision date: November/03/2015

2. HAZARD CLASSIFICATION

2.1. Classification of the substance or mixture:

TRANSPORT CLASSIFICATION WITH RULES OF EXEMPTION. SEE CHAPTER 14.

Self Classification

2.1.1 Classification according to Regulation (EC) No 1272/2008 [CLP/GHS]

Hazard Classes and Hazard Categories	Hazard Statements	Classification Procedure
Flam. Liq. 2	H225	Calculation method
Aquatic Acute Tox	H400	Calculation method

2.1.2 Classification according to 67/548/EEC or 1999/45/EC

F; R11, N; R50

2.1.3 Additional information:

Full text of R-, H- and EUH-phrases: see section 16.

2.2. Label elements

2.2.1 Labelling according to Regulation (EC) No 1272/2008 [CLP/GHS]

Hazard components for labeling:

hexamethyldisiloxane

Authorisation No n/a

Hazard pictograms



Flame GHS02



Environment GHS09

Safety Data Sheet

According to Regulation (EC) N° 1907/2006 modified by regulation (EU) N° 453/2010

Trade name: Atos # 8011 Provox Skin Barrier (50 pcs)

Product. No: # 8011

Version: 1.0 / EN

Print date: 11/4/15

Specification No: 1.0

Page 4 of 25

Revision date: November/03/2015

Signal word:

Danger

Hazard statements:

H225 Highly flammable liquid and vapor

H400 Very toxic to aquatic life

Precautionary statements:

P210 Keep away from heat/ sparks/ open flames/ hot surfaces – No smoking

P233 Keep container tightly closed (optional)

P273 Avoid release to the environment

P240 Ground/ bond container and receiving equipment (optional)

P241 Use explosion-proof electrical/ ventilating/ light/ .../ equipment (optional)

P242 Use only non-sparking tools (optional)

P243 Take precautionary measures against static discharge (optional)

Supplemental Hazard information (EU):

Not applicable

Special rules for supplemental label elements for certain mixtures:

Not applicable

2.3 Other hazards

Adverse physicochemical effects: Flammable

Adverse human health effects and symptoms: Can cause central nervous system (CNS) depression. May cause drowsiness or dizziness. May cause respiratory irritation. May cause serious eye irritation.

Adverse environmental effects: Very toxic to aquatic life

Other adverse hazards: None indicated

Safety Data Sheet

According to Regulation (EC) N° 1907/2006 modified by regulation (EU) N° 453/2010

Trade name: Atos # 8011 Provox Skin Barrier (50 pcs)

Product. No: # 8011

Version: 1.0 / EN

Print date: 11/4/15

Specification No: 1.0

Page 5 of 25

Revision date: November/03/2015

3. COMPOSITION/INFORMATION ON INGREDIENTS

3.2. Mixtures

3.2.1 Description of the mixture

Solution of volatile and non-volatile silicones

3.2.2 Hazardous Ingredients

This product contains the substances listed below, which are defined as dangerous substances or hazardous chemicals as defined in Regulation (EC) No 1272/2008 and present at concentration > 0.1 %

CAS No.	EC No.	Index No	REACH No.	% [weight]	Name	Classification according to 67/548/EEC
107-46-0	203-492-7	n/a	01-211949608-31	> 75 %	Hexamethyl- disiloxane	F; R11; R50

CAS No.	EC No.	Index No	REACH No.	% [weight]	Name	Classification according to Regulation (EC) No 1272/2008
107-46-0	203-492-7	n/a	01-211949608-31	> 75 %	Hexamethyl- disiloxane	Flam.Liq. 2 Aquatic Acute 1 Aquatic Chronic 1

Note: Classification refers to classifications of raw substances at 100 % and are used as basis for classifying the mixture.

3.3 Additional Information

Full text of R-, H- and EUH-phrases: see section 16.

4. FIRST AID MEASURES

4.1 Description of first aid measures

4.1.1 General information:

Safety Data Sheet

According to Regulation (EC) N° 1907/2006 modified by regulation (EU) N° 453/2010

Trade name: Atos # 8011 Provox Skin Barrier (50 pcs)

Product. No: # 8011

Version: 1.0 / EN

Print date: 11/4/15

Specification No: 1.0

Page 6 of 25

Revision date: November/03/2015

When in doubt or if symptoms are observed, get medical advice.

4.1.1 Following inhalation:

No special measures are necessary.

4.1.4 Following skin contact:

No special measures are necessary.

4.1.2 Following eye contact:

No special measures are necessary.

4.1.5 Following ingestion:

No special measures are necessary.

4.1.6 Self-protection of the first aider:

No action shall be taken involving any personal risk

4.1.7 Notes for the doctor:

Hexamethyldisiloxane (CAS 107-46-0) is major component of the mixture.

4.2 Most important symptoms and effects, both acute and delayed

No information available..

4.3 Indication of any immediate medical attention and special treatment needed

None

5. FIRE-FIGHTING MEASURES

5.1 Extinguishing media:

Suitable extinguishing media:

Safety Data Sheet

According to Regulation (EC) N° 1907/2006 modified by regulation (EU) N° 453/2010

Trade name: Atos # 8011 Provox Skin Barrier (50 pcs)

Product. No: # 8011

Version: 1.0 / EN

Print date: 11/4/15

Specification No: 1.0

Page 7 of 25

Revision date: November/03/2015

Alcohol resistant foam. Carbon dioxide (CO₂), Extinguishing powder. Water mist

Unsuitable extinguishing media:

Do not use a direct water jet on the burning product.

5.2 Special hazards arising from the substance or mixture

Hazardous combustion products:

In case of fire may be liberated: Carbon dioxide (CO₂). Carbon monoxide. Nitrogen oxides (NO_x).

5.3 Advice for fire-fighters

Do not inhale explosion and combustion gases. Use water spray jet to protect personnel and to cool endangered containers. Do not allow run-off from fire-fighting to enter drains or water courses.

Very toxic to aquatic life.

5.4 Additional information:

Wear a self-contained breathing apparatus and chemical protective clothing.

Safety Data Sheet

According to Regulation (EC) N° 1907/2006 modified by regulation (EU) N° 453/2010

Trade name: Atos # 8011 Provox Skin Barrier (50 pcs)

Product. No: # 8011

Version: 1.0 / EN

Print date: 11/4/15

Specification No: 1.0

Page 8 of 25

Revision date: November/03/2015

6. ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

6.1.1 For non-emergency personnel

Do not smoke. Do not expose to flame or any potential source of ignition (e.g. electrical equipment). Avoid contact with skin and inhalation of vapors. Ensure adequate ventilation of the workplace.

No action shall be taken involving any personal risk or without suitable training. Evacuate surrounding areas. Keep unnecessary and unprotected personnel from entering. Do not touch or walk through spilt material. Shut off all ignition sources. No flares, smoking or flames in hazard area. Avoid breathing vapor or mist. Provide adequate ventilation. Wear appropriate respirator when ventilation is inadequate. Put on appropriate personal protective equipment.

6.1.2 For emergency responders

Personal protective equipment:

Wear self contained breathing apparatus if necessary. Evacuate surrounding areas. Keep unnecessary and unprotected personnel from entering. Do not touch or walk through spilt material. Shut off all ignition sources. No flares, smoking or flames in hazard area. Avoid breathing vapor or mist. Provide adequate ventilation. Wear appropriate respirator when ventilation is inadequate. Put on appropriate personal protective equipment.

6.2 Environmental precautions:

Avoid dispersal of spilt material and runoff and contact with soil, waterways, drains and sewers. Inform the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil or air).

6.3 Methods and material for containment and cleaning up

6.3.1 For containment:

Stop leak if without risk. Move containers from spill area. Approach the release from upwind. Prevent entry into sewers, water courses, basements or confined areas. Wash spillages into an effluent treatment plant or proceed as follows. Contain and collect spillage with non-combustible, absorbent material e.g. sand, earth, vermiculite or diatomaceous earth and place in container for disposal according to local regulations. Use spark-proof tools and explosion-proof equipment. Dispose of via a licensed waste disposal contractor. Contaminated absorbent material may pose the same hazard as the spilt product.

Safety Data Sheet

According to Regulation (EC) N° 1907/2006 modified by regulation (EU) N° 453/2010

Trade name: Atos # 8011 Provox Skin Barrier (50 pcs)

Product. No: # 8011

Version: 1.0 / EN

Print date: 11/4/15

Specification No: 1.0

Page 9 of 25

Revision date: November/03/2015

6.3.2 For cleaning up:

Small spills: Allow to evaporate if it is safe to do so or contain and absorb using earth, sand or other inert material then transfer into suitable containers for recovery or disposal. Ventilate contaminated area thoroughly. Large spills: Dike or dam to contain for later disposal. Contact emergency authorities.

6.3.3 Other information:

None

6.4 Reference to other sections

For exposure control and personal protection measures, see section 8. For considerations of waste disposal, see section 13.

6.5 Additional information:

None

Safety Data Sheet

According to Regulation (EC) N° 1907/2006 modified by regulation (EU) N° 453/2010

Trade name: Atos # 8011 Provox Skin Barrier (50 pcs)

Product. No: # 8011

Version: 1.0 / EN

Print date: 11/4/15

Specification No: 1.0

Page 10 of 25

Revision date: November/03/2015

7. HANDLING AND STORAGE

7.1 Precautions for safe handling

7.1.1 Protective measures:

Provide adequate ventilation as well as local exhaustion at critical locations. When using do not eat, drink, smoke, sniff. Wash hands before breaks and after work. All work processes must always be designed so that the following is as low as possible: Inhalation of vapors or spray/mists. In case of gas escape or of entry into waterways, soils or drains, inform the responsible authorities. Wear personal protection equipment (see chapter 8). Use explosion-proof machinery, apparatus, ventilation facilities, tools etc. Use only antistatically equipped (spark-free) tools. Take precautionary measures against static discharges. Keep away from sources of ignition –No smoking. Vapors can form explosive mixtures with air.

Fire preventions:

Store and use away from heat, sparks, open flame or any other ignition source. Use explosion-proof electrical (ventilating, lighting and material handling) equipment. Use only non-sparking tools. Take precautionary measures against electrostatic discharges.

Aerosol and dust generation preventions:

Avoid breathing vapor or mist. Use only with adequate ventilation. Wear appropriate respirator when ventilation is inadequate.

Environmental precautions:

Avoid direct discharge to sewer, surface water and groundwater, not make to penetrate into the soil.

7.1.2 Advice on general occupational hygiene

7.2 Conditions for safe storage, including any incompatibilities

Technical measures and storage conditions:

Store in accordance with local regulations. Store in a segregated and approved area. Store in original container protected from direct sunlight in a dry, cool and well-ventilated area, away from incompatible materials (see section 10) and food and drink. Store locked up. Eliminate all ignition sources. Separate from oxidizing materials. Keep container tightly closed and sealed until ready for use. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Do not store in unlabeled containers. Use appropriate containment to avoid environmental contamination.

Safety Data Sheet

According to Regulation (EC) N° 1907/2006 modified by regulation (EU) N° 453/2010

Trade name: Atos # 8011 Provox Skin Barrier (50 pcs)

Product. No: # 8011

Version: 1.0 / EN

Print date: 11/4/15

Specification No: 1.0

Page 11 of 25

Revision date: November/03/2015

Packaging materials, hints on storage assembly:

Store in original containers. Keep away from: Oxidizing agent, Acid, alkali. Storage class 3.

7.3 Specific end uses:

Recommendations: Wet wipes

Industrial sector specific solutions: Health Care

Safety Data Sheet

According to Regulation (EC) N° 1907/2006 modified by regulation (EU) N° 453/2010

Trade name: Atos # 8011 Provox Skin Barrier (50 pcs)

Product. No: # 8011

Version: 1.0 / EN

Print date: 11/4/15

Specification No: 1.0

Page 12 of 25

Revision date: November/03/2015

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

8.1 Control parameters

8.1.1 Occupational Exposure Limits

No information is available for Occupational Exposure Levels (OELs).

8.1.3 Exposure limits at intended use:

No information is available for Exposure Levels (ELs). Avoid direct discharge to sewer, surface water and groundwater, not make to penetrate into the soil.

8.1.4 DNEL/PEC-values

Hexamethyldisiloxane: 890 mg/m³

8.1.5 Risk management measures according to used control banding approach

Handling should be at a temperature as low as possible. Ensure proper ventilation.

8.2 Exposure Controls

When using do not eat, drink, smoke, sniff. Wash hands before breaks and after work.

8.2.1 Appropriate engineering controls:

Handle in accordance with good industrial hygiene and safety practices. Wash hands, forearms and face thoroughly after handling chemical products, before eating, smoking and using the lavatory and at the end of the working period. Provide adequate ventilation as well as local exhaust at critical locations. If technical exhaust or ventilation measures are not possible or insufficient, respiratory protection must be worn.

8.2.2 Personal protection equipment:

8.2.2.1 Eye / Face protection: Safety glasses with side-shields.

8.2.2.2 Skin protection: Appropriate footwear and any additional skin protection measures should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.

Hand protection: Chemical-resistant, impervious gloves with long cuffs, complying with an

Safety Data Sheet

According to Regulation (EC) N° 1907/2006 modified by regulation (EU) N° 453/2010

Trade name: Atos # 8011 Provox Skin Barrier (50 pcs)

Product. No: # 8011

Version: 1.0 / EN

Print date: 11/4/15

Specification No: 1.0

Page 13 of 25

Revision date: November/03/2015

approved standard should be worn at all times when handling chemical products if a risk assessment indicates this is necessary. The selected protective gloves have to satisfy the specifications of EU Directive 89/686/EEC and the standard EN 374 derived from it.

Body protection: Personal protective equipment for the body should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.

8.2.2.3 Respiratory protection:

Respiratory protection necessarily at: exceeding exposure limit values insufficient ventilation. Insufficient exhaust handling larger quantities. Container device with compressed air (DIN EN137). /Filtering device (full mask or mouthpiece) with filter: Filter types A, B, E, K. Class 1: Maximum permitted contaminant concentration in inhaled air = 1000 mL/m³ (0,1% by vol.); Class 2: maximum permitted contaminant concentration in inhaled air = 5000 mL/m³ (0,5% by vol.); class 3: maximum permitted contaminant concentration in inhaled air = 10000 mL/m³ (1,0% by vol.).

8.2.2.4 Thermal hazards:

Handling should be at a temperature as low as possible. Ensure proper ventilation.

8.3. Environmental exposure controls:

Send to hazardous waste incinerator facility under observation of official regulations.

Measures related to consumer uses of the substance (as such or in mixtures):

Avoid direct discharge to sewer, surface water and groundwater, not make to penetrate into the soil.

Safety Data Sheet

According to Regulation (EC) N° 1907/2006 modified by regulation (EU) N° 453/2010

Trade name: Atos # 8011 Provox Skin Barrier (50 pcs)

Product. No: # 8011

Version: 1.0 / EN

Print date: 11/4/15

Specification No: 1.0

Page 14 of 25

Revision date: November/03/2015

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Important health, safety and environmental information

9.1.1 Appearance

Physical state: Textile wipe impregnated with transparent liquid

Colour: n/a

Odour: Characteristic

9.2.2 Safety relevant basic data

Parameter	Value	Remark
pH	-	no water in the blend
Melting point/range (°C)	ca -68	Hexamethyldisiloxane
Initial boiling point/range (°C, 1013 kPa)	ca 100	Hexamethyldisiloxane
Flash point (°C)	ca -6	Hexamethyldisiloxane
Vapour pressure (kPa, 20°C)	ca 44	Hexamethyldisiloxane
Ignition temperature (°C)	ca 340	Hexamethyldisiloxane
Density (g/cm ³ , 25°C)	0.76	Hexamethyldisiloxane
Water solubility	Insoluble	Hexamethyldisiloxane
Partition coefficient n-Octanol/Water (log Po/w)	>4	Hexamethyldisiloxane
Viscosity, dynamic (mPas, 25°C)	0,5	Hexamethyldisiloxane

9.2 Physical hazards:

Explosives: Not applicable

Flammable gases: Not applicable

Flammable aerosols: Not applicable

Oxidizing gases: Not applicable

Safety Data Sheet

According to Regulation (EC) N° 1907/2006 modified by regulation (EU) N° 453/2010

Trade name: Atos # 8011 Provox Skin Barrier (50 pcs)

Product. No: # 8011

Version: 1.0 / EN

Print date: 11/4/15

Specification No: 1.0

Page 15 of 25

Revision date: November/03/2015

Gases under pressure: Not applicable

Flammable liquids: Flammable liquid and vapor.

Flammable solids: Not applicable

Self-reactive substances and mixtures: Not applicable

Pyrophoric liquids Pyrophoric solids: Not applicable

Self-heating substances and mixtures: Not applicable

Substances or mixtures which, in contact with water emit flammable gases: Not applicable

Oxidizing liquids: Not applicable

Oxidizing solids: Not applicable

Organic peroxides: Not applicable

Metal corrosion: Not applicable

9.3 Other safety information

Properties of explosive atmospheres (mixtures):

Gases and vapors: lower 0,7 %, upper 26 %

Physical-chemical properties of nanoparticles:

Not applicable

Limiting oxygen concentration

Not applicable

Bulk density

0.76 g/cm³

Solubility in different media

Insoluble in water

Stability in organic solvents and identity of relevant degradation products

No data available

Evaporation rate

1.7 (butyl acetate = 1)

Conductivity

No data available

Safety Data Sheet

According to Regulation (EC) N° 1907/2006 modified by regulation (EU) N° 453/2010

Trade name: Atos # 8011 Provox Skin Barrier (50 pcs)

Product. No: # 8011

Version: 1.0 / EN

Print date: 11/4/15

Specification No: 1.0

Page 16 of 25

Revision date: November/03/2015

Surface tension

No data available

Dissociation constant in water (pKa)

Insoluble in water

Oxidation-reduction Potential

No data available

Fat solubility (solvent – oil to be specified)

No data available

Safety Data Sheet

According to Regulation (EC) N° 1907/2006 modified by regulation (EU) N° 453/2010

Trade name: Atos # 8011 Provox Skin Barrier (50 pcs)

Product. No: # 8011

Version: 1.0 / EN

Print date: 11/4/15

Specification No: 1.0

Page 17 of 25

Revision date: November/03/2015

10. STABILITY AND REACTIVITY

10.1 Reactivity

No information available.

10.2 Chemical stability

No information available.

10.3 Possibility of hazardous reactions

No information available.

10.4 Conditions to avoid

Avoid all possible sources of ignition (spark or flame). Do not pressurize, cut, weld, braze, solder, drill, grind or expose containers to heat or sources of ignition. -No smoking.

10.5 Incompatible materials:

Exothermic reaction with: Oxidizing Materials. Strong Acids. Strong Alkalis.

10.6 Hazardous decomposition products:

Decomposition with: Carbon dioxide (CO₂). Carbon monoxide. Nitrogen oxides (NO_x).

Safety Data Sheet

According to Regulation (EC) N° 1907/2006 modified by regulation (EU) N° 453/2010

Trade name: Atos # 8011 Provox Skin Barrier (50 pcs)

Product. No: # 8011

Version: 1.0 / EN

Print date: 11/4/15

Specification No: 1.0

Page 18 of 25

Revision date: November/03/2015

11. TOXICOLOGICAL INFORMATION

This mixture is classified as dangerous according to 1999/45/EC. This mixture is classified as hazardous according to regulation (EC) No. 1272/2008 (CLP). The classification was carried out according to the calculation method of the Preparations Directive (1999/45/EC).

11.2 Information on toxicological effects

11.2.1 Substances

Acute toxicity

	Effect Dose	Species	Remark
Acute oral toxicity	LD50: >5000 mg/kg	Rat	Hexamethyldisiloxane
Acute dermal toxicity	LD50: >2000 mg/kg	Rabbit	
Acute inhalation toxicity	LC50: c. 106 mg/l (4 hours)	Rat	Hexamethyldisiloxane

Skin corrosion/irritation

No data available

Serious eye damage/irritation

No data available

Irritation to respiratory tract

No data available

Respiratory or skin sensitisation

No data available

CMR effects (carcinogenicity, mutagenicity and Toxicity for reproduction)

Carcinogenicity: No data available

in-vitro Mutagenicity: No data available

Safety Data Sheet

According to Regulation (EC) N° 1907/2006 modified by regulation (EU) N° 453/2010

Trade name: Atos # 8011 Provox Skin Barrier (50 pcs)

Product. No: # 8011

Version: 1.0 / EN

Print date: 11/4/15

Specification No: 1.0

Page 19 of 25

Revision date: November/03/2015

Genotoxicity: No data available
in-vivo Mutagenicity: No data available
Germ cell mutagenicity: No data available
Toxicity for reproduction: No data available

Summarized evaluation of the CMR properties:

No data available

Symptoms related to the physical, chemical and toxicological characteristics:

In case of ingestion: No data available

In case of skin contact: No data available

In case of inhalation: No data available

In case of eye contact: No data available

11.4 Other information

This products should never be ingested. Keep away from food and drink.

Safety Data Sheet

According to Regulation (EC) N° 1907/2006 modified by regulation (EU) N° 453/2010

Trade name: Atos # 8011 Provox Skin Barrier (50 pcs)

Product. No: # 8011

Version: 1.0 / EN

Print date: 11/4/15

Specification No: 1.0

Page 20 of 25

Revision date: November/03/2015

12. ECOLOGICAL INFORMATION

12.1 Toxicity

Hexamethyldisiloxane, NOEC

Chronic (long term) toxicity to daphnia magna (Big water flea) – Effective dose 0,08 mg/L – 504 h

Acute (short term) toxicity to algae – daphnia magna (Big water flea) > 0,37 mg/L – 48 h

Chronic (long term) toxicity to algae – Cyprinus carpio (Common Carp) > = 0,04 mg/L

12.2 Persistence and degradability

Analytical method, Degree of elimination: Degradation rate 2%, 672 h;

Evaluation: Poorly biodegradable

12.3 Bioaccumulative potential

No data available

12.4 Mobility in soil

No data available

12.5 Results of PBT and vPvB assessment

Hexamethyldisiloxane:

The substance does not meet the PBT/vPvB criteria of REACH, annex XIII

12.6 Other adverse effects:

Hexamethyldisiloxane:

Very toxic to aquatic life. The evaluation was carried out according to the calculation method of the preparation directive.

12.7 Additional information: not available

Safety Data Sheet

According to Regulation (EC) N° 1907/2006 modified by regulation (EU) N° 453/2010

Trade name: Atos # 8011 Provox Skin Barrier (50 pcs)

Product. No: # 8011

Version: 1.0 / EN

Print date: 11/4/15

Specification No: 1.0

Page 21 of 25

Revision date: November/03/2015

13. DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Send to hazardous waste incinerator facility under observation of official regulations. Clean IBC's or drums at approved facility only. Contaminated packages must be completely emptied and can be re-used following proper cleaning. Packing which cannot be properly cleaned must be disposed of. Handle contaminated packages in the same way as the substance itself.

Safety Data Sheet

According to Regulation (EC) N° 1907/2006 modified by regulation (EU) N° 453/2010

Trade name: Atos # 8011 Provox Skin Barrier (50 pcs)

Product. No: # 8011

Version: 1.0 / EN

Print date: 11/4/15

Specification No: 1.0

Page 22 of 25

Revision date: November/03/2015

14. TRANSPORT INFORMATION

14.1 Land transport (ADR/RID/GGVSE):

UN-No: 3175 WITH RULES OF EXEMPTION. SEE SECTION 14.5.

Proper shipping name: SOLIDS CONTAINING FLAMMABLE LIQUID, N.O.S.

(HEXAMETHYLDISILOXANE)

Name according to bill of freight: Solids containing flammable liquid, n.o.s.

(HEXAMETHYLDISILOXANE)

Transport Class(es): 4.1 Flammable solids WITH RULES OF EXEMPTION. SEE SECTION 14.5.

Risk Code: 40 WITH RULES OF EXEMPTION. SEE SECTION 14.5.

Packing group: II WITH RULES OF EXEMPTION. SEE SECTION 14.5.

Hazard label(s): Flammable WITH RULES OF EXEMPTION. SEE SECTION 14.5.

14.2 Sea transport (IMDG-Code/GGVSee):

UN No: 3175 WITH RULES OF EXEMPTION. SEE SECTION 14.5.

Proper shipping name: SOLIDS CONTAINING FLAMMABLE LIQUID, N.O.S.

(HEXAMETHYLDISILOXANE)

IMDG Class(es): 4.1 Flammable solids WITH RULES OF EXEMPTION. SEE SECTION 14.5.

Packing group: II WITH RULES OF EXEMPTION. SEE SECTION 14.5.

14.3 Air transport (ICAO-IATA/DGR):

UN No: 3175

Proper shipping name: SOLIDS CONTAINING FLAMMABLE LIQUID, N.O.S.

(HEXAMETHYLDISILOXANE)

ICAO/IATA Class(es): 4.1 Flammable solids

Packing group: II

Special provision(s): Flammable

14.4 Special precautions for user: none

Safety Data Sheet

According to Regulation (EC) N° 1907/2006 modified by regulation (EU) N° 453/2010

Trade name: Atos # 8011 Provox Skin Barrier (50 pcs)

Product. No: # 8011

Version: 1.0 / EN

Print date: 11/4/15

Specification No: 1.0

Page 23 of 25

Revision date: November/03/2015

14.4 Environmental hazards

Land transport (ADR/RID): Yes

Sea transport (IMDG): Yes (P)

14.5 Additional information

ADR/RID chapter 3.3 Special rule 216

Mixtures of solids which are not subjected to the requirements of ADR and flammable liquids may be carried under this entry without first applying the classification criteria of Class 4.1, provided there is no free liquid visible at the time the packaging, vehicle or container is closed. Sealed packets and articles containing less than 10 ml of a packing group II or III flammable liquid absorbed into a solid material are not subject to ADR provided there is no free liquid in the packet or article.

IMDG Code chapter 3.3 special rule 216

Mixtures of solids which are not subject to the provisions of this Code and flammable liquids may be transported under this entry without first applying the classification criteria of class 4.1, provided there is no free liquid visible at the time the substance is loaded or at the time the packaging or cargo transport unit is closed. Each cargo transport unit shall be leak proof when used as a bulk container. Sealed packets and articles containing less than 10 mL of a packing group II or III flammable liquid absorbed into a solid material are not subject to the provisions of this Code provided there is no free liquid in the packet or article.

Safety Data Sheet

According to Regulation (EC) N° 1907/2006 modified by regulation (EU) N° 453/2010

Trade name: Atos # 8011 Provox Skin Barrier (50 pcs)

Product. No: # 8011

Version: 1.0 / EN

Print date: 11/4/15

Specification No: 1.0

Page 24 of 25

Revision date: November/03/2015

15. REGULATORY INFORMATION

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

15.1.1 EU regulations

Water hazard class (WGK)

Class: 1 (Slightly hazardous to water) Classification according to WvWvS

Information according 1999/13/EC about limitation of emissions of volatile organic compounds (VOC-guideline): This information is not available

15.2 Chemical Safety Assessment:

Chemical safety assessment for substances has not been carried out.

Safety Data Sheet

According to Regulation (EC) N° 1907/2006 modified by regulation (EU) N° 453/2010

Trade name: Atos # 8011 Provox Skin Barrier (50 pcs)

Product. No: # 8011

Version: 1.0 / EN

Print date: 11/4/15

Specification No: 1.0

Page 25 of 25

Revision date: November/03/2015

16. OTHER INFORMATION

16.1 Indication of changes

November 3rd 2015 First release

16.2 Abbreviations and acronyms: none

16.3 Key literature references and sources for data

REACH registration information
Supplier Material Data Sheet (SDS)

16.4 Classification for mixtures and used evaluation method according to regulation (EC) 1207/2008 [CLP]:

Calculation method based on the classification of hazardous components.

16.5 Relevant R-, H- and EUH-phrases (number and full text):

H225	Highly flammable liquid and vapor
H400	Very toxic to aquatic life
H410	Very toxic to aquatic life with long lasting effects
R11	Highly flammable
R50	Very toxic to aquatic organisms
R51/53	Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment
S61	Avoid release to the environment. Refer to special instructions/safety data sheet

16.6 Training advice:

The Safety Data Sheet is intended to provide information for a health and safety assessment of the material during transport, storage, or applied in the workplace. Attention to users is drawn to hazards resulting from improper use of the product.

16.7 Further information:

This sheet contains the data concerning the product that are known at the date of release. Document produced and managed by means of computer. Valid without signature.