Safety Data Sheet

According to Annex II to REACH - Regulation 2015/830

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

1.1. Product identifier

Code: **ELASTOPROOF COMP. A**
Product name **ELASTOPROOF COMP. A**

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

Intended use **Part of a protective coating**

1.3. Details of the supplier of the safety data sheet

Name **DRACO ITALIANA S.p.A.**
Full address **Via Monte Grappa, 11 D-E**
District and Country **20067 Tribiano (MI)**
Italia
Tel. +39 02.90632917
Fax +39 02.90631976

e-mail address of the competent person responsible for the Safety Data Sheet **info@draco-edilizia.it**

1.4. Emergency telephone number

For urgent inquiries refer to **Centro Antiveleni di Bergamo 800883300 (Azienda Ospedaliera Papa Giovanni XXII)**
Centro Antiveleni di Firenze 0557947819 (Az. Osp. "Careggi" U.O. Tossicologia Medica)
Centro Antiveleni di Foggia 80018345 (Az. Osp. Univ. Foggia)
Centro Antiveleni di Milano 0266101029 (Osp. Niguarda Ca' Granda)
Centro Antiveleni di Napoli 0817472870 (Az. Osp. "A. Cardarelli")
Centro Antiveleni di Pavia 038224444 (CAV Centro Nazionale di Informazione Tossicologica)
Centro Antiveleni di Roma 063054343 (CAV Policlinico "A. Gemelli")
Centro Antiveleni di Roma 0649978000 (CAV Policlinico "Umberto I")
Centro Antiveleni di Roma 06 68593726 (CAV "Osp. Pediatrico Bambino Gesù" Dip. Emergenza e Accettazione DEA)

SECTION 2. Hazards identification

2.1. Classification of the substance or mixture

The product is classified as hazardous pursuant to the provisions set forth in (EC) Regulation 1272/2008 (CLP) (and subsequent amendments and supplements). The product thus requires a safety datasheet that complies with the provisions of (EU) Regulation 2015/830. Any additional information concerning the risks for health and/or the environment are given in sections 11 and 12 of this sheet.

Hazard classification and indication:

Skin sensitization, category 1	H317	May cause an allergic skin reaction.
Hazardous to the aquatic environment, chronic toxicity, category 3	H412	Harmful to aquatic life with long lasting effects.

2.2. Label elements

Hazard labelling pursuant to EC Regulation 1272/2008 (CLP) and subsequent amendments and supplements.

Hazard pictograms:

SECTION 2. Hazards identification ... / >>

Signal words: Warning

Hazard statements:

H317	May cause an allergic skin reaction.
H412	Harmful to aquatic life with long lasting effects.
EUH205	Contains epoxy constituents. May produce an allergic reaction.

Precautionary statements:

P280	Wear protective gloves.
P261	Avoid breathing dust / fume / gas / mist / vapours / spray.
P333+P313	If skin irritation or rash occurs: Get medical advice / attention.
P362+P364	Take off contaminated clothing and wash it before reuse.
P273	Avoid release to the environment.

Contains: Reaction product: bisphenol-A-epichlorohydrin and epoxy resins (average molecular weight <= 700)
Oxirane, mono [(C12-14- alkyloxy) methyl] derivatives
Reaction product: bisphenol-F-epichlorohydrin and epoxy resins (average molecular weight <= 700)

2.3. Other hazards

On the basis of available data, the product does not contain any PBT or vPvB in percentage ≥ than 0,1%.

SECTION 3. Composition/information on ingredients

3.2. Mixtures

Contains:

Identification	x = Conc. %	Classification 1272/2008 (CLP)
Reaction product: bisphenol-A-epichlorohydrin and epoxy resins (average molecular weight <= 700)		
CAS *25068-38-6*	1 ≤ x < 2,5	**Eye Irrit. 2 H319, Skin Irrit. 2 H315, Skin Sens. 1 H317, Aquatic Chronic 2 H411**
EC *500-033-5*		
INDEX *603-074-00-8*		
Reg. no. *01-2119456619-26-XXXX*		
Reaction product: bisphenol-F-epichlorohydrin and epoxy resins (average molecular weight <= 700)		
CAS *9003-36-5*	0,5 ≤ x < 1	**Skin Irrit. 2 H315, Skin Sens. 1 H317, Aquatic Chronic 2 H411**
EC *500-006-8*		
INDEX		
Reg. no. *01-2119454392-40-XXXX*		
Nonil fenolo		
CAS *25154-52-3*	0,25 ≤ x < 0,5	**Repr. 2 H361fd, Acute Tox. 4 H302, Skin Corr. 1B H314, Eye Dam. 1 H318, Aquatic Acute 1 H400 M=1, Aquatic Chronic 1 H410 M=1**
EC *246-672-0*		
INDEX *601-053-00-8*		
Oxirane, mono [(C12-14- alkyloxy) methyl] derivatives		
CAS *68609-97-2*	0 ≤ x < 0,5	**Skin Irrit. 2 H315, Skin Sens. 1 H317**
EC *271-846-8*		
INDEX *603-103-00-4*		
Reg. no. *01 2119485289-22-XXXX*		

The full wording of hazard (H) phrases is given in section 16 of the sheet.

SECTION 4. First aid measures

4.1. Description of first aid measures

EYES: Remove contact lenses, if present. Wash immediately with plenty of water for at least 15 minutes, opening the eyelids fully. If problem persists, seek medical advice.
SKIN: Remove contaminated clothing. Wash immediately with plenty of water. If irritation persists, get medical advice/attention. Wash contaminated clothing before using it again.
INHALATION: Remove to open air. In the event of breathing difficulties, get medical advice/attention immediately.
INGESTION: Get medical advice/attention. Induce vomiting only if indicated by the doctor. Never give anything by mouth to an unconscious person, unless authorised by a doctor.

SECTION 4. First aid measures ... / >>

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

Specific information on symptoms and effects caused by the product are unknown.

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

Information not available

SECTION 5. Firefighting measures

5.1. Extinguishing media

SUITABLE EXTINGUISHING EQUIPMENT
The extinguishing equipment should be of the conventional kind: carbon dioxide, foam, powder and water spray.
UNSUITABLE EXTINGUISHING EQUIPMENT
None in particular.

5.2. Special hazards arising from the substance or mixture

HAZARDS CAUSED BY EXPOSURE IN THE EVENT OF FIRE
Do not breathe combustion products.

5.3. Advice for firefighters

GENERAL INFORMATION
Use jets of water to cool the containers to prevent product decomposition and the development of substances potentially hazardous for health. Always wear full fire prevention gear. Collect extinguishing water to prevent it from draining into the sewer system. Dispose of contaminated water used for extinction and the remains of the fire according to applicable regulations.
SPECIAL PROTECTIVE EQUIPMENT FOR FIRE-FIGHTERS
Normal fire fighting clothing i.e. fire kit (BS EN 469), gloves (BS EN 659) and boots (HO specification A29 and A30) in combination with self-contained open circuit positive pressure compressed air breathing apparatus (BS EN 137).

SECTION 6. Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Block the leakage if there is no hazard.
Wear suitable protective equipment (including personal protective equipment referred to under Section 8 of the safety data sheet) to prevent any contamination of skin, eyes and personal clothing. These indications apply for both processing staff and those involved in emergency procedures.

6.2. Environmental precautions

The product must not penetrate into the sewer system or come into contact with surface water or ground water.

6.3. Methods and material for containment and cleaning up

Collect the leaked product into a suitable container. Evaluate the compatibility of the container to be used, by checking section 10. Absorb the remainder with inert absorbent material.
Make sure the leakage site is well aired. Contaminated material should be disposed of in compliance with the provisions set forth in point 13.

6.4. Reference to other sections

Any information on personal protection and disposal is given in sections 8 and 13.

SECTION 7. Handling and storage

7.1. Precautions for safe handling

Before handling the product, consult all the other sections of this material safety data sheet. Avoid leakage of the product into the environment. Do not eat, drink or smoke during use. Remove any contaminated clothes and personal protective equipment before entering places in which people eat.

7.2. Conditions for safe storage, including any incompatibilities

Store only in the original container. Store the containers sealed, in a well ventilated place, away from direct sunlight. Keep containers away from any incompatible materials, see section 10 for details.

SECTION 7. Handling and storage ... / >>

7.3. Specific end use(s)

Information not available

SECTION 8. Exposure controls/personal protection

8.1. Control parameters

Reaction product: bisphenol-A-epichlorohydrin and epoxy resins (average molecular weight <= 700)								
Predicted no-effect concentration - PNEC								
Normal value in fresh water						3	µg/l	
Normal value in marine water						0,3	µg/l	
Normal value for fresh water sediment						0,5	mg/kg/d	
Normal value for marine water sediment						0,5	mg/kg/d	
Normal value for water, intermittent release						0,013	mg/l	
Normal value of STP microorganisms						10	mg/l	
Normal value for the terrestrial compartment						0,05	mg/kg/d	
Health - Derived no-effect level - DNEL / DMEL								
	Effects on consumers				Effects on workers			
Route of exposure	Acute local	Acute systemic	Chronic local	Chronic systemic	Acute local	Acute systemic	Chronic local	Chronic systemic
Oral		0,75 mg/kg bw/d		0,75 mg/kg bw/d				
Inhalation		0,75 mg/m3		0,75 mg/m3		12,3 mg/m3		12,3 mg/m3
Skin		3,6 mg/kg bw/d		3,6 mg/kg bw/d	8,3	8,3 mg/kg bw/d		8,3 mg/kg bw/d

Reaction product: bisphenol-F-epichlorohydrin and epoxy resins (average molecular weight <= 700)								
Predicted no-effect concentration - PNEC								
Normal value in fresh water						0,003	mg/l	
Normal value in marine water						0,0003	mg/l	
Normal value for fresh water sediment						0,294	mg/kg/d	
Normal value for marine water sediment						0,0294	mg/kg/d	
Normal value for water, intermittent release						0,0254	mg/l	
Normal value of STP microorganisms						10	mg/l	
Normal value for the terrestrial compartment						0,237	mg/kg/d	
Health - Derived no-effect level - DNEL / DMEL								
	Effects on consumers				Effects on workers			
Route of exposure	Acute local	Acute systemic	Chronic local	Chronic systemic	Acute local	Acute systemic	Chronic local	Chronic systemic
Oral				6,25 mg/kg bw/d				
Inhalation				8,7 mg/m3				29,39 mg/m3
Skin				62,5 mg/kg bw/d		8,3 µg/cm2		104,15 mg/kg bw/d

VND = hazard identified but no DNEL/PNEC available ; NEA = no exposure expected ; NPI = no hazard identified.

8.2. Exposure controls

As the use of adequate technical equipment must always take priority over personal protective equipment, make sure that the workplace is well aired through effective local aspiration.
When choosing personal protective equipment, ask your chemical substance supplier for advice.
Personal protective equipment must be CE marked, showing that it complies with applicable standards.
Provide an emergency shower with face and eye wash station.
HAND PROTECTION
Protect hands with category III work gloves (see standard EN 374).
The following should be considered when choosing work glove material: compatibility, degradation, failure time and permeability.
The work gloves' resistance to chemical agents should be checked before use, as it can be unpredictable. The gloves' wear time depends on the duration and type of use.
SKIN PROTECTION
Wear category II professional long-sleeved overalls and safety footwear (see Regulation 2016/425 and standard EN ISO 20344). Wash body

SECTION 8. Exposure controls/personal protection ... / >>

with soap and water after removing protective clothing.
EYE PROTECTION
Wear airtight protective goggles (see standard EN 166).
RESPIRATORY PROTECTION
If the threshold value (e.g. TLV-TWA) is exceeded for the substance or one of the substances present in the product, use a mask with a type B filter whose class (1, 2 or 3) must be chosen according to the limit of use concentration. (see standard EN 14387). In the presence of gases or vapours of various kinds and/or gases or vapours containing particulate (aerosol sprays, fumes, mists, etc.) combined filters are required. Respiratory protection devices must be used if the technical measures adopted are not suitable for restricting the worker's exposure to the threshold values considered. The protection provided by masks is in any case limited.
If the substance considered is odourless or its olfactory threshold is higher than the corresponding TLV-TWA and in the case of an emergency, wear open-circuit compressed air breathing apparatus (in compliance with standard EN 137) or external air-intake breathing apparatus (in compliance with standard EN 138). For a correct choice of respiratory protection device, see standard EN 529.
ENVIRONMENTAL EXPOSURE CONTROLS
The emissions generated by manufacturing processes, including those generated by ventilation equipment, should be checked to ensure compliance with environmental standards.
Product residues must not be indiscriminately disposed of with waste water or by dumping in waterways.

SECTION 9. Physical and chemical properties

9.1. Information on basic physical and chemical properties

Properties		Value	Information
Appearance		paste	
Colour		beige	
Odour		characteristic	
Odour threshold		Not available	
pH		Not determined	
Melting point / freezing point		Not available	
Initial boiling point		Not available	
Boiling range		Not available	
Flash point	>	60 °C	
Evaporation rate		Not available	
Flammability (solid, gas)		Not available	
Lower inflammability limit		Not available	
Upper inflammability limit		Not available	
Lower explosive limit		Not available	
Upper explosive limit		Not available	
Vapour pressure		Not available	
Vapour density		Not available	
Relative density		1,3 g/cm3	
Solubility		soluble in organic solvents	
Partition coefficient: n-octanol/water		Not determined	
Auto-ignition temperature		Not available	
Decomposition temperature		Not available	
Viscosity		Not available	
Explosive properties		Not available	
Oxidising properties		Not available	

9.2. Other information

VOC (Directive 2010/75/EC) : 1,11 % - 14,43 g/litre

SECTION 10. Stability and reactivity

10.1. Reactivity

There are no particular risks of reaction with other substances in normal conditions of use.

10.2. Chemical stability

The product is stable in normal conditions of use and storage.

10.3. Possibility of hazardous reactions

No hazardous reactions are foreseeable in normal conditions of use and storage.

SECTION 10. Stability and reactivity ... / >>

10.4. Conditions to avoid

None in particular. However the usual precautions used for chemical products should be respected.

10.5. Incompatible materials

Information not available

10.6. Hazardous decomposition products

Information not available

SECTION 11. Toxicological information

11.1. Information on toxicological effects

Oxirane, mono [(C12-14- alkyloxy) methyl] derivatives
Inhalation: May cause respiratory tract irritation.
Ingestion: Gastrointestinal symptoms, including stomach pain.
Skin contact: Irritating to skin. May cause sensitization by skin contact.
Contact with eyes: Irritating to eyes.

Metabolism, toxicokinetics, mechanism of action and other information

Information not available

Information on likely routes of exposure

Information not available

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

Information not available

Interactive effects

Information not available

ACUTE TOXICITY

ATE (Inhalation) of the mixture:	Not classified (no significant component)
ATE (Oral) of the mixture:	Not classified (no significant component)
ATE (Dermal) of the mixture:	Not classified (no significant component)

Reaction product: bisphenol-A-epichlorohydrin and epoxy resins (average molecular weight <= 700)

LD50 (Oral)	> 11400 mg/kg Rat

Reaction product: bisphenol-F-epichlorohydrin and epoxy resins (average molecular weight <= 700)

LD50 (Oral)	> 2000 mg/kg Rat, OECD 420
LD50 (Dermal)	> 5000 mg/kg Rat, OECD 401

Oxirane, mono [(C12-14- alkyloxy) methyl] derivatives

LD50 (Oral)	17100 mg/kg Rat

Nonil fenolo

LD50 (Oral)	580 mg/kg Rat
LD50 (Dermal)	2031 mg/kg Rabbit

Reaction product: bisphenol-A-epichlorohydrin and epoxy resins (average molecular weight <= 700)
Acute toxicity - inhalation: Due to the very low vapor pressure (saturated atmosphere = 0.008 ppb), significant studies on the effects of acute inhalation could not be performed.

Acute toxicity - dermal: In a rat study according to the OECD standard n. 402 the dermal LD50 was> 2000 mg / kg. In several acute dermal toxicity studies in rabbits, LD50 was> 2000 mg / kg. In a rabbit study a LD50 value of 23 grams / kg was reported.

SECTION 11. Toxicological information ... / >>

Reaction product: bisphenol-F-epichlorohydrin and epoxy resins (average molecular weight <= 700)
Acute toxicity - inhalation: in accordance with Annex VII of the REACH Regulation, it is not necessary to conduct the acute toxicity study by inhalation absorption, since oral and dermal absorption studies are available for this substance.

In a rat study according to the OECD standard n. 402 the dermal LD50 was> 2000 mg / kg. In several acute dermal toxicity studies in rabbits, LD50 was> 2000 mg / kg. In a rabbit study a LD50 value of 23 grams / kg was reported.

Oxirane, mono [(C12-14- alkyloxy) methyl] derivatives
Acute toxicity - inhalation: No mortality was observed in rats exposed for 7 hours to saturated vapor (150 mg / m3).
LC50 (4h) 0.206 mg / l, Inhalation, Dusts / mists, Rat (0 Death.)

SKIN CORROSION / IRRITATION

Does not meet the classification criteria for this hazard class

Reaction product: bisphenol-A-epichlorohydrin and epoxy resins (average molecular weight <= 700)
Result: skin - erythema / eschar 404 Acute Dermal Irritation / Corrosion
Species: rabbit
Score 1.5 -2

Result: Skin - Edema 404 Acute Dermal Irritation / Corrosion
Species: Rabbit
Score: 1.0 - 1.5

Result: eyes - 405 Acute Eye Irritation / Corrosion
Species: Rabbit
Score: 0

Result: Conjunctive redness
Species: Rabbit
Score: 0.7

Result: Skin - Moderately irritating
Species: Rabbit
Exposure: 24 h

Result: Skin - Strongly irritating
Species: rabbit
Exposure: 24 h

Result: eyes - mild irritant
Species: rabbit

Reaction product: bisphenol-F-epichlorohydrin and epoxy resins (average molecular weight <= 700)
Result: Skin - erythema / eschar 404 Acute Dermal Irritation / Corrosion
Species: rabbit
Score: 0.7
Exposure: 4 h
Observation: 72 h

Result: Skin - edema 404 Acete Dermal Irritation / Corrosion
Species: rabbit
Score: 0
Exposure: 4 h
Observation: 4-504 h

Result: eyes - corneal opacity 405 Acute Eye Irritation / corrosion
Species: Rabbit
Score: 0
Observation: 1 - 168 h

Result: eyes - Injury of the iris 405 Acute Eye Irritation / Corrosion
Species: Rabbit
Score: 0
Observation: 1 - 168 h

Result: eyes - Redness of the conjunctiva 405 Acute Eye Irritation / Corrosion
Species: rabbit

SECTION 11. Toxicological information ... / >>

Score: 0Observation: 1 - 168 h

Result: eyes - conjunctiva edema 405 Acute Eye Irritation / Corrosion
Species: rabbit
Score: 0
Observation: 1 - 168 h

Result: Skin - Slight irritation
Species: rabbit
Exposure: 24 h

Oxirane, mono [(C12-14- alkyloxy) methyl] derivatives
Result: Skin - Primary index of skin irritation (PDII) OTS 798.4450 Acute Dermal Irritation
Species: Rabbit
Score: 4.1
Exposure: 24 h
Observation: 72 h

Result: Skin - Primary Index of Skin Irritation (PDII) 404 Acute Dermal Irritation / Corrosion
Species: Rabbit
Score: 5.75
Exposure: 24 h
Observation: 72 h

Result: eyes - corneal opacity 405 Acute Eye Irritation / Corrosion
Species: Rabbit
Score: 2
Observation: 1 - 24 h

Species: Skin - Moderately irritating
Species: Rabbit
Exposure: 24 h

SERIOUS EYE DAMAGE / IRRITATION

Does not meet the classification criteria for this hazard class

RESPIRATORY OR SKIN SENSITISATION

Sensitising for the skin

Reaction product: bisphenol-F-epichlorohydrin and epoxy resins (average molecular weight <= 700)
Species: rabbit
Test: OECD 405
Result: no eye irritation

Skin sensitization
Reaction product: bisphenol-A-epichlorohydrin and epoxy resins (average molecular weight <= 700)
In a study with an LLNA assay on mice conducted according to the OECD standard n. 429, the estimated EC3 corresponded to a concentration of 5.7%; this result suggests that BADGE is a moderate skin sensitizer in this test system. In a guinea pig maximization study according to the OECD standard n. 406, BADGE induced a positive skin reaction in 100% of the experimental animals at a stimulus dose with a concentration of 50%. Therefore, BADGE is an "extreme" skin sensitizer in the conditions of this study. BADGE was positive for skin sensitization also in a study with the Buehler method on guinea pig conducted according to OCSE standard n. 406

Reaction product: bisphenol-F-epichlorohydrin and epoxy resins (average molecular weight <= 700)
The Buehler method was used to assess the skin sensitization potential of the liquid epoxy BPFDGE. Ten male guinea pigs were given 0.4 ml of the test substance topically once a week for three weeks. A positive control of BPFDGE liquid epoxy resin was used on ten additional animals. The stimulation phase began two weeks later with the addition of 5 animals exposed to 0.4ml of liquid BPFDGE liquid epoxy resin. The negative control had 0 positive reactions; BPFDGE liquid epoxy resin produced positive reactions in 4 out of 10 guinea pigs and the positive control had 8 out of ten positive reactions. Under the conditions of this study, the test material resulted in delayed hypersensitivity in guinea pigs.

Route of exposure: skin
Species: mouse
Method: OECD 429
Result: can cause sensitization in contact with the skin

SECTION 11. Toxicological information ... / >>

Oxirane, mono [(C12-14- alkyloxy) methyl] derivatives
In a sensitization study with the Buehler method carried out according to the test specification OTS 870.2600 of the US EPA, positive skin reactions were observed in 20/20 guinea pigs. An extreme sensitizer in a study with maximization test on guinea pig conducted according to the OECD test specification No. 406.

GERM CELL MUTAGENICITY

Does not meet the classification criteria for this hazard class

Reaction product: bisphenol-A-epichlorohydrin and epoxy resins (average molecular weight <= 700)
In several studies it was found that BADGE induces gene mutation in experimental strains Ames / Salmonella TA1535 and TA100. In general, mutagenic activity was greater without S9 metabolic activation of the liver. Induced gene mutation in L5178Y mouse lymphoma cells. Induced gene mutation and chromosomal damage in V79 Chinese hamster cells. Induced cell transformation in Syrian hamster BHK cells based on clonal growth in soft agar. It did not induce evidence of chromosomal damage in a study with an oral probe in a test of the dominant lethal on mice conducted up to a high dosage level of 10 grams / kg and in a micronuclear test on mice conducted up to a high dose of 5000 mg / kg. Negative in a spermatocytic cytogenetic assay on male mice with treatment for 5 days by oral probe up to a high dose of 3000 mg / kg. It did not induce an increase in the frequency of chromosomal damage in a cytogenetic assay on bone marrow cells on a Chinese hamster using an oral probe up to a high dose of 3300 mg / kg. It did not induce an increase in DNA strand breaks in rat liver cells after treatment with oral gavage with 500 mg / kg, measured by alkaline elution.

Reaction product: bisphenol-F-epichlorohydrin and epoxy resins (average molecular weight <= 700)
Bisphenol F diglycidyl ether induced a gene mutation in the Ames / Salmonella mutation test and chromosomal aberrations in human lymphocytes in multiple independent GLP studies conducted according to test guidelines. Furthermore, the structural analog, bisphenol A diglycidyl ether (BPADGE), induced a significant increase in the frequency of mutations in cultured L5178Y mouse lymphoma cells, supporting the other conclusions. Therefore, BPFDGE is genotoxic in vitro.When the genotoxic potential of bisphenol F diglycidyl ether was evaluated in multiple GLP compliant in vivo tests, including mouse micronucleus tests, UDS in vivo / in vitro tests, and MutaMouse on rat, no evidence of genotoxicity was observed. Results from other in vivo genotoxicity tests also support these negative results for BPFDGE. It is concluded that bisphenol F diglycidyl ether is not genotoxic in vivo.

In vitro genotoxicity:
Metabolic activation: with or without metabolic activation
Method: OECD 471
Result: positive

Metabolic activation: with or without metabolic activation
Method: OECD 473
Result: positive

Metabolic activation: with or without metabolic activation
Method: OECD 476
Result: positive

Genotoxicity in vivo:
Type of gellule: germs
Method of application: oral
Result: negative

Type of gellula: somatic
Method of application: oral
Dose: 0 - 5000 mg / kg
Result: negative

Oxirane, mono [(C12-14- alkyloxy) methyl] derivatives
Positive in a bacterial mutation test conducted according to the OECD test specification No. 471 in an experimental Salmonella TA1535 strain with and without metabolic activation with S9. Negative in a gene mutation test on Chinese hamster ovary cells (CHO) HGPRT conducted according to the OECD test specification No. 476 up to cytotoxic levels with and without metabolic activation with S9. Negative in a gene mutation assay on L5178Y / TK mouse lymphoma cells tested up to cytotoxic dose levels. Negative by micronucleus induction (chromosomal damage) in a mouse study conducted according to OECD specification No. 474 up to a high dose of intraperitoneal injection of 4.0 grams / kg. Negative in a study of chromosomal aberrations on rat bone marrow conducted similarly to the OECD test specification No. 475 by intraperitoneal injection, up to a high dose of about 700 mg / kg.

CARCINOGENICITY

Does not meet the classification criteria for this hazard class

SECTION 11. Toxicological information ... / >>

Reaction product: bisphenol-A-epichlorohydrin and epoxy resins (average molecular weight <= 700)
In a study with an oral rat probe according to the OECD standard n. 453 there was no evidence of carcinogenicity up to the high dose level of 100 mg / kg / day. Dermal exposure studies were performed in male mice and female rats according to OECD regulation n. 453. No evidence of carcinogenicity was observed in male mice treated up to the high dose of 100 mg / kg / day and female rats exposed up to the high dose of 1000 mg / kg / day.

Reaction product: bisphenol-F-epichlorohydrin and epoxy resins (average molecular weight <= 700)
È stata valutata la capacità del Bisfenolo F diglicidiletere (BPFDGE) di indurre tumori locali e sistemici in uno studio di 24 mesi con test cutaneo ("skin painting") sul topo. Il trattamento cutaneo di topi per due volte alla settimana con una soluzione fino al 10% di diglicidiletere bisfenolo F (BPFDGE) non ha indotto alcun risultato negativo di incidenza di tumori o effetti cutanei locali. Pertanto, il BPFDGE non è da considerare cancerogeno per il topo nelle condizioni di questo studio. Il NOAEL è stato stimato pari a circa 800 mg/kg/die.

Specie: ratto, maschio e femmina
Modalità di applicazione: orale
Tempo diesposizione: 24 mesi
Dosi: 15 mg/kg
Frequenza del trattamento: 7 al giorno
Metodo: OECD 453
Risultato: negativo

Specie: topo, maschio
Modalità di applicazione: dermico
Tempo di esposizione: 24 mesi
Dosi: 1 mg/kg
Frequenza del trattamento: 3 al giorno
Metodo: OECD 453
Risultato: negativo

Specie: ratto, femmina
Modalità di applicazione: dermico
Tempo di esposizione: 24 mesi
Dosi: 1 mg/kg
Frequenza del trattamento: 5 al giorno
Metodo: OECD 453
Risultato: negativo

REPRODUCTIVE TOXICITY

Does not meet the classification criteria for this hazard class

Reaction product: bisphenol-A-epichlorohydrin and epoxy resins (average molecular weight <= 700)
BADGE did not induce any evidence of developmental toxicity in rats and rabbits exposed by oral probe, or in cutaneously treated rabbits, in BPL studies according to the OECD standard n. 414. Studies with an oral probe were conducted up to a high dose level of 180 mg / kg / day which produced maternal toxicity based on the reduction in body weight gain. The rabbit skin toxicity study was conducted up to a high dose of 300 mg / kg / day which induced maternal toxicity based on the reduction in body weight gain.

Reaction product: bisphenol-F-epichlorohydrin and epoxy resins (average molecular weight <= 700)
The bisphenol A diglycidylether (DGEBPA) has been tested for its embryo / fetal toxicity and teratogenicity in pregnant rabbits. The DGEBPA was applied daily to the back (depilated) of white New Zealand rabbits at doses of 0 (polyethylene glycol, vehicle control), 30, 100 or 300 mg / kg of body weight / day at a volumetric dose of 1 ml / kg of body weight / day on days 6 to 18 of gestation. Twenty-six inseminated rabbits were used per dosage group, obtaining a minimum of 20 pregnant rabbits per exposure level. An occlusive bandage of absorbent gauze and non-absorbent cotton was placed on the dosing area on the back of each rabbit. The bandage was held in place for a minimum of 6 hours / day with a lycra / spandex protective cover. Following the period of occlusion the bandage and the protective wrapper were removed. Maternal toxicity effects were observed among pregnant rabbits in the 300 mg / kg dose group, as evidenced by moderate to severe erythema, fissures, haemorrhages and mild edema at the site of exposure. Similar, but less severe skin lesions were observed in pregnant rabbits in the 100 mg / kg / day exposure group. Effects on the skin (mild erythema) observed in pregnant rabbits in the 30 mg / kg / day group were not considered toxicologically significant. No evidence of embryo / fetotoxicity or teratogenicity was observed at any dose, which results in a level at which no effect (NOEL) is observed at an embryonic / fetal level of 300 mg / kg body weight / day.

Oxirane, mono [(C12-14- alkyloxy) methyl] derivatives
In a dermal toxicological study conducted in the rat according to the US EPA OTS 798.4420 method and according to the OECD test specification No. 414, the NOAEL for adverse effects on both mother and development was above the high dose level of 200 mg / kg / day.

Adverse effects on sexual function and fertility

SECTION 11. Toxicological information ... / >>

Reaction product: bisphenol-F-epichlorohydrin and epoxy resins (average molecular weight <= 700)
Species: rat, male and female
Method of application: oral
Method: OECD 416
Result: There was no effect on fertility and early embryonic development.

Adverse effects on development of the offspring
Reaction product: bisphenol-F-epichlorohydrin and epoxy resins (average molecular weight <= 700)
Species: rabbit, female
Method of application: dermal
General toxicity in mothers: no level of harmfulness
observed: 30 mg / kg body weight
Result: no teratogenic effect

STOT - SINGLE EXPOSURE

Does not meet the classification criteria for this hazard class

STOT - REPEATED EXPOSURE

Does not meet the classification criteria for this hazard class

Reaction product: bisphenol-F-epichlorohydrin and epoxy resins (average molecular weight <= 700)
NOAEL: 250 mg / kg
Species: rat, male and female
Method of application: ingestion
Exposure time: 13 weeks
Number of exposures: 7 d
Mode: subchronic toxicity

ASPIRATION HAZARD

Does not meet the classification criteria for this hazard class

SECTION 12. Ecological information

This product is dangerous for the environment and the aquatic organisms. In the long term, it have negative effects on aquatic environment.

12.1. Toxicity

Reaction product: bisphenol-F-epichlorohydrin and epoxy resins (average molecular weight <= 700)
EC50 (Selenastrum capricornutum): 1.8 mg / l
Exposure time: 72 h
Static test
Method: OECD 201

CI50 (activated sludge)> 100 mg / l
Exposure time: 3 h
Static test

Oxirane, mono [(C12-14- alkyloxy) methyl] derivatives
LC50, 96 hour:> 5000 mg / l, Oncorhynchus mykiss (rainbow trout)
LC50, 96 hour: 1800 mg / l, Lepomis macrochirus (Perch)
EC50, 72 hours: 843 mg / l, Pseudokirchneriella subcapitata
NOEC, 72 hours: 500 mg / l, Pseudokirchneriella subcapitata
EC50, 3 hours:> 100 mg / l, Activated sludge

Reaction product: bisphenol-A-epichlorohydrin and epoxy resins (average molecular weight <= 700)

LC50 - for Fish	1,3 mg/l/96h 203 Fish, Acute Toxicity Test
EC50 - for Crustacea	2,1 mg/l/48h 202 Daphnia sp. Acute Immobilization Test and Reproduction Test
EC50 - for Algae / Aquatic Plants	> 11 mg/l/72h Algae
Chronic NOEC for Crustacea	0,3 mg/l 11 Daphnia Magna Reproduction Test (21 d)

Reaction product: bisphenol-F-epichlorohydrin and epoxy resins (average molecular weight <= 700)

LC50 - for Fish	2,54 mg/l/96h Fish
EC50 - for Crustacea	2,55 mg/l/48h 202 Daphnia sp. Acute Immobilization Test and Reproduction Tes
EC50 - for Algae / Aquatic Plants	> 1000 mg/l/72h 201 Alga, Growth Inhibition Test

SECTION 12. Ecological information ... / >>

Chronic NOEC for Crustacea	0,3 mg/l Daphnia magna, 21 d, OECD 211 semistatic

Oxirane, mono [(C12-14- alkyloxy) methyl] derivatives

LC50 - for Fish	> 5 g/l 203 Fish, Acute Toxicity Test. Bluegill
EC50 - for Crustacea	7,2 mg/l/48h 202 Daphnia sp. Acute Immobilization Test and Reproduction Test
EC50 - for Algae / Aquatic Plants	844 mg/l/72h 201 Alga, Growth Inhibition Test

Nonil fenolo

LC50 - for Fish	0,19 mg/l/96h Oncorynchus mykiss
EC50 - for Crustacea	0,19 mg/l/48h Daphnia magna
EC50 - for Algae / Aquatic Plants	1,48 mg/l/72h Pseudokirchneriella subcapitata

12.2. Persistence and degradability

Reaction product: bisphenol-A-epichlorohydrin and epoxy resins (average molecular weight <= 700)
The level of biodegradation in an "improved" OECD 301F study was 5% within the 28-day contact period. Biodegradation has reached 6 - 12% after 28 days of contact in a study conducted according to the OECD standard n. 301B. Therefore BADGE is not readily biodegradable under the conditions of the studies.

Reaction product: bisphenol-F-epichlorohydrin and epoxy resins (average molecular weight <= 700)
Bisphenol F diglycidyl ether was not readily biodegradable under the conditions of the screening studies according to OECD test specifications Nos. 301 B and 301 D. The maximum rate of biodegradation observed in one of the OECD 301 B studies was 16% per 10 mg / the 28 days of contact.

Inoculum: activated sludge
Concentration: 3 mg / l
Result: not biodegradable
Biodegradation: approx. 0%
Exposure time: 28 d
Method: Directive 67/548 / EEC Annex V C.4.E

Oxirane, mono [(C12-14- alkyloxy) methyl] derivatives
In a study conducted according to OECD Test Specification No. 301 F, biodegradation was 57-655 after 7 days. However, in a study conducted according to OECD Test Specification No. 301 D (unopened bottle) biodegradation was only 34.7% after 28 days.
87% degradation: 28 days OECD 301F

12.3. Bioaccumulative potential

Reaction product: bisphenol-A-epichlorohydrin and epoxy resins (average molecular weight <= 700)
LogPOW: 2.64 - 3.78
BCF: 3 - 31 31.00
Potential: low

Reaction product: bisphenol-F-epichlorohydrin and epoxy resins (average molecular weight <= 700)
BCF: 150 150.00
Potential: low

Oxirane, mono [(C12-14- alkyloxy) methyl] derivatives
BCF: 160 - 263 160.00
Potential: low

Reaction product: bisphenol-F-epichlorohydrin and epoxy resins (average molecular weight <= 700)

Partition coefficient: n-octanol/water	2,7 Log Kow
BCF	150

Oxirane, mono [(C12-14- alkyloxy) methyl] derivatives

Partition coefficient: n-octanol/water	3,77 Log Kow

12.4. Mobility in soil

Reaction product: bisphenol-F-epichlorohydrin and epoxy resins (average molecular weight <= 700)

Partition coefficient: soil/water	4460 OECD 121

12.5. Results of PBT and vPvB assessment

SECTION 12. Ecological information ... / >>

On the basis of available data, the product does not contain any PBT or vPvB in percentage ≥ than 0,1%.

12.6. Other adverse effects

Information not available

SECTION 13. Disposal considerations

13.1. Waste treatment methods

Reuse, when possible. Product residues should be considered special hazardous waste. The hazard level of waste containing this product should be evaluated according to applicable regulations.
Disposal must be performed through an authorised waste management firm, in compliance with national and local regulations.
CONTAMINATED PACKAGING
Contaminated packaging must be recovered or disposed of in compliance with national waste management regulations.

SECTION 14. Transport information

The product is not dangerous under current provisions of the Code of International Carriage of Dangerous Goods by Road (ADR) and by Rail (RID), of the International Maritime Dangerous Goods Code (IMDG), and of the International Air Transport Association (IATA) regulations.

14.1. UN number

Not applicable

14.2. UN proper shipping name

Not applicable

14.3. Transport hazard class(es)

Not applicable

14.4. Packing group

Not applicable

14.5. Environmental hazards

Not applicable

14.6. Special precautions for user

Not applicable

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

Information not relevant

SECTION 15. Regulatory information

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

Seveso Category - Directive 2012/18/EC: None

Restrictions relating to the product or contained substances pursuant to Annex XVII to EC Regulation 1907/2006

Product		
Point	3 - 40	
Contained substance		
Point	75	Calcium Carbonate Reg. no.: Esentato ai sensi dell'allegato V.7

SECTION 15. Regulatory information ... / >>

Point	75	Black iron oxide Reg. no.: 01-2119457646-28-0015
Point	75	Reaction product: bisphenol-A-epichlorohydrin and epoxy resins (average molecular weight <= 700) Reg. no.: 01-2119456619-26-XXXX
Point	46-75	Nonil fenolo
Point	75	Oxirane, mono [(C12-14- alkyloxy) methyl] derivatives Reg. no.: 01 2119485289-22-XXXX
Point	75	Ottametilciclotetrasilossano Reg. no.: 01-2119529238-36-XXXX

Regulation (EC) No. 2019/1148 - on the marketing and use of explosives precursors
Not applicable

Substances in Candidate List (Art. 59 REACH)
Nonil fenolo

Substances subject to authorisation (Annex XIV REACH)
None

Substances subject to exportation reporting pursuant to (EC) Reg. 649/2012:
Nonil fenolo - (NONYLPHENOLS)

Substances subject to the Rotterdam Convention:
None

Substances subject to the Stockholm Convention:
None

Healthcare controls
Workers exposed to this chemical agent must not undergo health checks, provided that available risk-assessment data prove that the risks related to the workers' health and safety are modest and that the 98/24/EC directive is respected.

15.2. Chemical safety assessment

A chemical safety assessment has not been performed for the preparation/for the substances indicated in section 3.

SECTION 16. Other information

Text of hazard (H) indications mentioned in section 2-3 of the sheet:

Repr. 2	Reproductive toxicity, category 2
Acute Tox. 4	Acute toxicity, category 4
Skin Corr. 1B	Skin corrosion, category 1B
Eye Irrit. 2	Eye irritation, category 2
Skin Irrit. 2	Skin irritation, category 2
Skin Sens. 1	Skin sensitization, category 1
Aquatic Acute 1	Hazardous to the aquatic environment, acute toxicity, category 1
Aquatic Chronic 1	Hazardous to the aquatic environment, chronic toxicity, category 1
Aquatic Chronic 2	Hazardous to the aquatic environment, chronic toxicity, category 2
Aquatic Chronic 3	Hazardous to the aquatic environment, chronic toxicity, category 3
H361fd	Suspected of damaging fertility. Suspected of damaging the unborn child.
H302	Harmful if swallowed.
H314	Causes severe skin burns and eye damage.
H319	Causes serious eye irritation.
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.
H411	Toxic to aquatic life with long lasting effects.
H412	Harmful to aquatic life with long lasting effects.
EUH205	Contains epoxy constituents. May produce an allergic reaction.

LEGEND:
- ADR: European Agreement concerning the carriage of Dangerous goods by Road
- CAS NUMBER: Chemical Abstract Service Number
- CE50: Effective concentration (required to induce a 50% effect)

SECTION 16. Other information ... / >>

- CE NUMBER: Identifier in ESIS (European archive of existing substances)- CLP: EC Regulation 1272/2008
- DNEL: Derived No Effect Level
- EmS: Emergency Schedule
- GHS: Globally Harmonized System of classification and labeling of chemicals
- IATA DGR: International Air Transport Association Dangerous Goods Regulation
- IC50: Immobilization Concentration 50%
- IMDG: International Maritime Code for dangerous goods
- IMO: International Maritime Organization
- INDEX NUMBER: Identifier in Annex VI of CLP
- LC50: Lethal Concentration 50%
- LD50: Lethal dose 50%
- OEL: Occupational Exposure Level
- PBT: Persistent bioaccumulative and toxic as REACH Regulation
- PEC: Predicted environmental Concentration
- PEL: Predicted exposure level
- PNEC: Predicted no effect concentration
- REACH: EC Regulation 1907/2006
- RID: Regulation concerning the international transport of dangerous goods by train
- TLV: Threshold Limit Value
- TLV CEILING: Concentration that should not be exceeded during any time of occupational exposure.
- TWA STEL: Short-term exposure limit
- TWA: Time-weighted average exposure limit
- VOC: Volatile organic Compounds
- vPvB: Very Persistent and very Bioaccumulative as for REACH Regulation
- WGK: Water hazard classes (German).

GENERAL BIBLIOGRAPHY

1. Regulation (EC) 1907/2006 (REACH) of the European Parliament
2. Regulation (EC) 1272/2008 (CLP) of the European Parliament
3. Regulation (EU) 790/2009 (I Atp. CLP) of the European Parliament
4. Regulation (EU) 2015/830 of the European Parliament
5. Regulation (EU) 286/2011 (II Atp. CLP) of the European Parliament
6. Regulation (EU) 618/2012 (III Atp. CLP) of the European Parliament
7. Regulation (EU) 487/2013 (IV Atp. CLP) of the European Parliament
8. Regulation (EU) 944/2013 (V Atp. CLP) of the European Parliament
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11. Regulation (EU) 2016/918 (VIII Atp. CLP) of the European Parliament
12. Regulation (EU) 2016/1179 (IX Atp. CLP)
13. Regulation (EU) 2017/776 (X Atp. CLP)
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15. Regulation (EU) 2018/1480 (XIII Atp. CLP)
16. Regulation (EU) 2019/521 (XII Atp. CLP)
17. Regulation (EU) 2019/1148
18. Regulation (EU) 2020/217 (XIV Atp. CLP)

- The Merck Index. - 10th Edition
- Handling Chemical Safety
- INRS - Fiche Toxicologique (toxicological sheet)
- Patty - Industrial Hygiene and Toxicology
- N.I. Sax - Dangerous properties of Industrial Materials-7, 1989 Edition
- IFA GESTIS website
- ECHA website
- Database of SDS models for chemicals - Ministry of Health and ISS (Istituto Superiore di Sanità) - Italy

Note for users:
The information contained in the present sheet are based on our own knowledge on the date of the last version. Users must verify the suitability and thoroughness of provided information according to each specific use of the product.
This document must not be regarded as a guarantee on any specific product property.
The use of this product is not subject to our direct control; therefore, users must, under their own responsibility, comply with the current health and safety laws and regulations. The producer is relieved from any liability arising from improper uses.
Provide appointed staff with adequate training on how to use chemical products.

CALCULATION METHODS FOR CLASSIFICATION

SECTION 16. Other information ... / >>

Chemical and physical hazards: Product classification derives from criteria established by the CLP Regulation, Annex I, Part 2. The data for evaluation of chemical-physical properties are reported in section 9.Health hazards: Product classification is based on calculation methods as per Annex I of CLP, Part 3, unless determined otherwise in Section 11.
Environmental hazards: Product classification is based on calculation methods as per Annex I of CLP, Part 4, unless determined otherwise in Section 12.

Changes to previous review:
The following sections were modified:
02 / 09 / 11 / 15.