Environmental Impact of Food Contact Substance (21 CFR Part 25)

Enviromnental Assessment

1. **Date:** April 1, 2019

2. **Name of Notifier:** Amorim & Irmãos

3. **Address:** Amorim & Irmãos
Rua de Meladas 380
4536-902 Mozelos, Portugal

All communication regarding this food contact notification (FCN) environmental assessment (EA) should be sent to the attention of the authorized representative:

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Exponent, Inc.
1150 Connecticut Ave NW, Suite 1100
Washington, DC 20036
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4. **Description of the proposed action:**

   a. **Requested action:**

The action requested in this submission is to permit the use of a toluene diisocyanate polyurethane polymer as a food contact substance (FCS), which is designed as a binder for cork granulate and is used in the production of micro-agglomerated cork stoppers. The trade name for the FCS is Biocol BS 3010. Biocol BS 3010 is a toluene diisocyanate (CASRN 26471-62-5) based polyurethane polymer with a free toluene diisocyanate (TDI) content of < 1%. The FCS will be used in the production of Amorim & Irmãos' Neutrocork® micro-agglomerated corks (henceforth, Neutrocork® stopper). The Neutrocork® stoppers are then used as closures for bottles containing wines and other alcoholic beverages. Neutrocork® stoppers are a so-called "technical" stopper recommended for wines intended for early consumption.

b. Need for action:

The FCS is intended for use as a binder of granulated cork in the production of micro-agglomerated corks that are used as stoppers for bottles of wines, sparkling wines, and select microbrewery beers. The FCS has been specifically tailored to bind the granulated cork together while maintaining desirable viscoelastic properties of the stopper. The flexibility and elasticity of polyurethane based binders such as the FCS are preferred over existing epoxy or silicone based adhesives, exhibiting a rigidity and flexibility more suited to use in cork stoppers.

c. Locations of use/disposal:

Use: As a component of finished micro-agglomerated cork stoppers, the FCS will be used to cork wine, sparkling wine, and microbrewery beer bottles nationwide. The FCS is used in patterns corresponding to the needs and locations of wine, sparkling wine, and microbrewery beer bottling facilities. Closures containing the FCS will be widely distributed across the United States (U.S.), and will be utilized in patterns corresponding to the national population density.

Disposal: The FCS, along with the micro-agglomerated cork stopper, will be disposed of in municipal solid waste (MSW) systems throughout the U.S., including rural and urban residential neighborhoods, businesses, etc. According to the U.S. Environmental Protection Agency (EPA)'s 2015 data regarding MSW in the U.S., approximately 262 million tons of MSW are generated annually, with approximately 65.3%, or 170 million tons, discarded and disposed of in MSW landfills or combusted. More precisely, 33.57 million tons, or 12.8% of MSW were combusted with energy recovery in 2015, and 137.70 million tons, or 52.5%, were landfilled (U.S. EPA, 2018a).

Assuming that food-contact articles containing the FCS are expected to be disposed of by landfilling or combustion, only about 80.4% of the FCS materials will be deposited in land disposal sites, and about 19.6% will be combusted[1].

[1] Utilizing figures cited in the 2018 EPA report, "Advancing Sustainable Materials Management," and assuming that food contact articles containing the FCS are expected to be disposed of by landfill or combustion (i.e. not recovered for recycling or composted), we calculated the disposal pattern for the FCS based only on the quantities of MSW that are land disposed or combusted. On this basis, approximately 19.6% of food-contact articles containing the FCS will be combusted annually, according to the following calculation: 12.8% combusted ÷ (12.8% combusted + 52.5% land disposed) = 19.6% combusted. The remaining 80.4% will be land disposed.

5. Identification of the substances that are the subject of the proposed action:

As described in Item 4(a), the FCS (Biocol BS 3010), is a polyurethane polymer, which is designed as a binder for cork granulate, based on isocyanate and polyol, in the production of micro-agglomerated cork stoppers. The FCS is a toluene diisocyanate (CASRN 26471-62-5) based polyurethane polymer with a free toluene diisocyanate (TDI) content of < 1%. Table 1 contains additional chemical identity information for the polyurethane polymer.

Generically, a polyurethane polymer results from the reaction of a polyfunctional polyol with a polyfunctional isocyanate (i.e., polyisocyanate). The chemical polymerization reaction involves the formation of urethane bonds that result from the addition reaction between the hydroxyl group of the polyol and the isocyanate group from the polyisocyanate (see Figure 1).

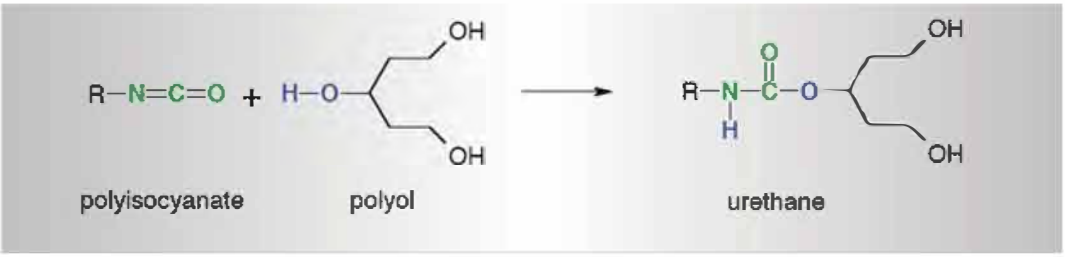
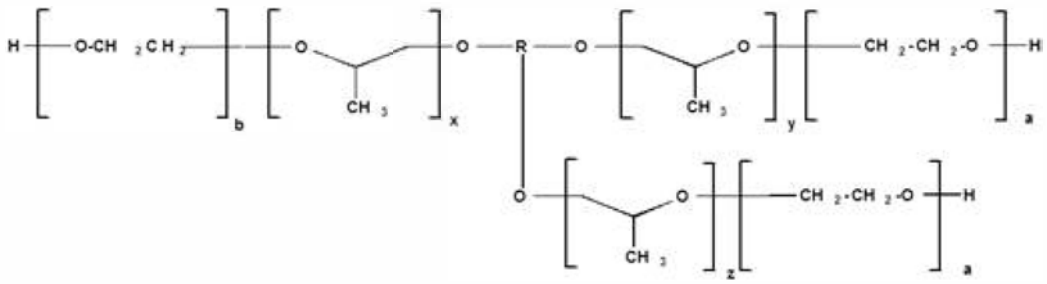
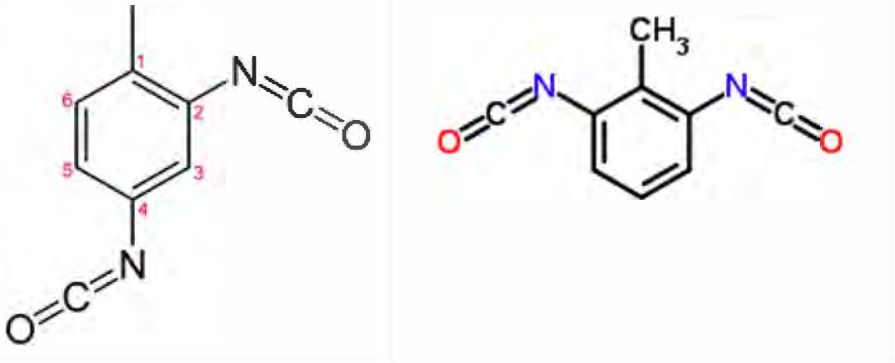


Figure 1. Chemical Polymerization Reaction

Table 1. Chemical Identity of Biocol BS 3010

Biocol BS 3010	
CASRN	68227-13-4
Systematic Name	Oxirane, 2-methyl-, polymer with oxirane, ether with 1,2,3-propanetriol (3:1), polymer with 1,3-diisocyanato-2-methylbenzene and 2,4-diisocyanato-1-methylbenzene Refined soybean oil (10.5% CASRN 8001-22-7) is added after polymerization.
Molecular Formula	(C9H6N2O2.C9H6N2O2.C3H8O3.3(C3H6O.C2H4O)x)x
Molecular Weight	Average 14,500 Dalton

Biocol BS 3010	
Chemical Structure	Starting polyol structure:  Reacted with TDI: 
Density (25ºC)	1.04 g/mL
Viscosity (25ºC)	3000 - 8000 mPa•S
Solid Content	≥ 96%
Appearance	Liquid
Free NCO[1] Value	2.0 – 3.5%

[1]NCO = formula for the isocyanate functional group. The % NCO is the weight percent of the nitrogen-carbon-oxygen group.

Additional information relating to the FCS is provided in EA Appendix I (Biocol BS 3010 Material Safety Data Sheet).

6. Introduction of substances into the environment:

a. Introduction of substances into the environment as a result of manufacture:

The FCS (Biocol BS 3010) and the finished micro-agglomerated cork stoppers are manufactured outside of the U.S. – in Portugal. Under 21 CFR §25.40(a), an environmental assessment ordinarily should focus on relevant environmental issues relating to the use and disposal from use, rather than the production, of FDA-regulated articles. Moreover, information available to the Notifier does not suggest that there are any extraordinary circumstances in this case indicative of any adverse environmental impact as a result of the manufacture of the FCS. Consequently, information on the manufacturing site and compliance with relevant emissions requirements is not provided here.

b. Introduction of substances into the environment as a result of use and disposal:

The maximum yearly market volume of the FCS is based on fifth-year sales projections of finished micro-agglomerated cork stoppers in the U.S. (Confidential Appendix 2).

The FCS is expected to be used in the manufacture of the Neutrocork® stopper, which are used as closures for bottles containing wines and other alcoholic beverages and will be entirely incorporated into and remain within the finished food contact article (Neutrocork® stopper). Waste materials generated in the production process are expected to be disposed of as a part of the food-contact article manufacturer's overall nonhazardous solid waste in accordance with established procedures, in this case outside the U.S.

As described in Item 4(c), food contact articles containing the FCS (Biocol BS 3010) sold and distributed within the U.S. will be disposed of through municipal solid waste (MSW) systems. Because the FCS is retained within the disposed micro-agglomerated cork stoppers after use, 100% of the FCS contained within the micro-agglomerated cork stoppers is expected to be discarded in MSW landfills or incinerated in MSW combustors.

Based on the maximum FCS use level and considering the projected fifth-year sales estimates, the FCS is demonstrated to comprise a negligible component of annual MSW discards. Calculations supporting this determination are included in Confidential Appendix 2.

When disposal of the entire finished cork article is considered using projected fifth-year sales estimates, the contribution of finished corks to annual MSW discards also accounts for a negligible component. Calculations supporting this determination are included in Confidential Appendix 2. Additionally, we note that polyurethane materials, having composition similar to the FCS are present in MSW. Therefore, the requested use of the FCS will not significantly alter the magnitude or composition of environmental releases of MSW disposed of in landfills.

Similarly, the FCS is demonstrated to comprise a negligible component of the amount of MSW combusted annually. Calculations supporting this determination are included in Confidential Appendix 2. The FCS is composed of carbon, hydrogen, nitrogen, and oxygen, elements commonly found in MSW. Air emissions from large and small MSW combustors are regulated by EPA with standards of performance and emissions guidelines (40 CFR Part 60). Additionally, emissions of certain "criteria air pollutants," e.g., carbon monoxide and nitrogen oxides, are controlled via National Ambient Air Quality Standards set by EPA (40 CFR Part 50). Ultimately, due to its negligible addition to the MSW stream and components, which are typical of MSW, incineration of the FCS will not significantly alter the emissions from properly-operating MSW combustors or result in a violation of applicable emissions laws and regulations for MSW combustors.

Because the above described composition of the FCS, incineration of articles manufactured with the FCS in MSW combustion facilities are expected to generate greenhouse gas (GHG) emissions such as carbon dioxide and nitrous oxide. As such, we have analyzed GHG emissions using the projected market volume and EPA's Greenhouse Gas Equivalencies Calculator (U.S. EPA, 2018). This analysis is provided in Confidential Appendix 2.

In accordance with 40 CFR 1508.27, the analysis of the significance of environmental impacts must include the degree to which the action threatens a violation of federal, state, or local laws imposed for the protection of the environment. In this context, the greenhouse gas (GHG) emissions resulting from the use and disposal of the FCS relate to the incineration of articles containing the FCS in municipal solid waste (MSW) combustion facilities. Such facilities are regulated by the U.S. Environmental Protection Agency (U.S. EPA) under 40 C.F.R. § 98, which "establishes mandatory GHG reporting requirements for owners and operators of certain facilities that directly emit GHG." Part 2 of this regulation (40 C.F.R. § 98.2) describes the facilities that must report to GHG emissions under EPA's GHG reporting program (GHGRP), and sets an annual 25,000 metric ton carbon dioxide equivalent (CO_2-e) emission threshold for required reporting.

Based on the information provided in Confidential Appendix 2, combustion of the FCS would result in GHG emissions well below the EPA threshold for mandatory reporting. As such, no significant environmental impact is anticipated resulting from the combustion of the FCS in MSW combustion facilities.

Moreover, MSW landfills are regulated by the U.S. EPA (40 CFR Part 258) to restrict movement of waste into the environment, including location restrictions, composite liner requirements, leachate collection and removal systems, operating practices, groundwater monitoring requirements, and closure and post-closure care requirements (U.S. EPA, 2018b).

No significant introduction, if any, of the FCS constituents are expected to enter the environment as a result of landfill disposal of food-contact items containing the FCS, in light of the EPA regulations governing MSW landfills. EPA's regulations require new MSW landfill units and lateral expansions of existing units to have composite liners and leachate collection systems to prevent leachate from entering ground and surface water, and to have ground water monitoring systems (40 CFR Part 258). Therefore the requested use of the FCS will not significantly alter the magnitude, composition, or environmental impacts of environmental releases from MSW disposed of in landfills. Based upon confidential migration testing of the FCS-containing cork material, very low levels of residual monomers were detected following extraction with 3% acetic acid. This testing also showed that no significant levels of total non-volatile extractives. The reference to the studies supporting these determinations is included in Confidential Appendix 2. Therefore, we do not expect the FCS to enter aquatic bodies as a result of this route of disposal either.

Based on the information in Item 6 and Confidential Appendix 2, no significant environmental introductions of the FCS are anticipated as a result of use and disposal of articles manufactured with the FCS.

7. Fate of substances released into the environment:

a. Air

No significant effect on the concentration of and exposure to any substance in the atmosphere is anticipated due to the proposed use of the FCS. As discussed in Item 5 above, the FCS (Biocol BS 3010) is a polymer and therefore characteristically non-volatile.

In addition, as discussed above in Item 6, the FCS is demonstrated to comprise a negligible component of the amount of MSW incinerated annually. Further, no significant emissions from the combustion of the FCS-containing cork stoppers in the MSW combusted is anticipated, and will not cause municipal waste combustors to violate any applicable laws or emissions regulations.

b. Water

No significant effect on the concentration of and exposure to any substance in fresh water, estuarine or marine ecosystems is anticipated due to the proposed use of the FCS. As mentioned above, the FCS is entirely incorporated into and remains within the manufactured food-contact articles. Biocol BS 3010 is not anticipated to dissolve or be removed from finished articles. Manufacture occurs entirely outside the U.S., and disposal is anticipated to be in municipal landfills or incineration facilities. As such, no introduction of the FCS into aquatic environments is anticipated, and the fate of the FCS in aqueous environments does not need to be addressed.

c. Land

As discussed in Item 6 above, no significant effect on the concentration of or exposure to substances in terrestrial ecosystems is anticipated from the proposed use of the FCS. The polymeric nature of the FCS is anticipated to result in virtually no leaching of the FCS components into the environment under normal conditions and proper adherence to use and disposal protocols. Therefore, there is no anticipated exposure of terrestrial organisms to Biocol BS 3010 as a result of the compound's use in cork stoppers.

Considering all above information, we respectfully submit that there is no reasonable expectation of significant environmental impacts resulting from the proposed use of Biocol BS 3010 in cork stoppers manufactured outside the U.S. and internally distributed.

8. Environmental effects of released substances:

Because no significant amounts of the FCS are expected to be released into the environment as the result of use and disposal, and because food contact materials manufactured with Biocol BS 3010 consist of extremely small quantities of combustion products and leachables, if any, it is unlikely that the FCS will be a risk to aquatic or

terrestrial organisms. Therefore, we do not further discuss fate or effects of the FCS in the environment.

9. Use of resources and energy:

The FCS will replace and/or compete with similar food contact substances currently in the market. As is the case with other food contact materials, the production, use and disposal of the FCS will involve the use of energy and natural resources such as petroleum products, coal, etc. However, the use of this FCS is not anticipated to result in a net increase in the use of energy or resources within the U.S., as the FCS is intended for use in cork stoppers which will be used in place of similar articles, such as 100% synthetic bottle closures.

As described in Item 6(a), the FCS is manufactured outside of the U.S. – in Portugal. For context, annual polyurethane production is estimated at 17.9 million metric tons worldwide, with 3.5 million metric tons being produced in the European Union (CIEC Promoting Science, 2017). When compared to the Global and European markets for polyurethane, the manufacture of the FCS for the requested use is negligible and is therefore not anticipated to impact the energy and other resources required for the manufacture of such materials.

In the U.S., the use and subsequent disposal of the FCS is not expected to result in a net increase in the energy and resources required to transport and/or dispose of wastes, as the amount of FCS disposed of annually in the U.S. is estimated to comprise a negligible component of MSW streams (see Item 6).

For the described reasons, the requested use of the FCS is not anticipated to have an adverse impact on energy and resources.

10. Mitigation measures:

As shown above, no significant adverse environmental impacts are expected to result from the use and disposal of the FCS. Thus, the use of the FCS as proposed is not reasonably expected to result in environmental problems requiring mitigation measures.

11. Alternatives to the proposed action:

No potential adverse environmental effects are identified herein which would necessitate alternative actions to that proposed in this request. The alternative of not approving the action proposed herein would simply be the continued use of materials such as 100% synthetic closures that are currently on the market. As such, the action would have no significant environmental impact.

12. List of Preparers:

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Dr. Tran has more than 20 years of experience in exposure and risk assessment, and has evaluated the safety of foods and food ingredients, additives, and contaminants extensively.

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Scientist
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Washington, DC 20036
Telephone: 202-772-4936
E-mail: RWilken@exponent.com

Ms. Wilken specializes in EPA FIFRA and state regulatory processes, with a robust interdisciplinary research background in aquatic ecology and environmental science.

13. Certification:

The undersigned official certifies that the information provided herein is true, accurate, and complete to the best of my knowledge.

Signature: [redacted]

Nga Tran
Principal Scientist, Exponent, Inc.

Date: April 1, 2019

14. References:

CIEC Promoting Science. (2017). Polyurethanes. In *The Essential Chemical Industry online*. The Centre for Industry Education Collaboration (CIEC). Last updated April 24, 2017. Available at: http://www.essentialchemicalindustry.org/polymers/polyurethane.html

U.S. Environmental Protection Agency (EPA). (2018). Greenhouse Gas Equivalencies Calculator. Last updated 15 October, 2018. Available at: http://www.epa.gov/energy/greenhouse-gas-equivalencies-calculator

U.S. Environmental Protection Agency (EPA). (July 2018a). Advancing Sustainable Materials Management: 2015 Fact Sheet: Assessing Trends in Material Generation, Recycling, Composting, Combustion with Energy Recovery and Landfilling in the United States. Washington, D.C., Office of Solid Waste and Emergency Response, EPA530-R-15-003. Table 4. Available at: https://www.epa.gov/sites/production/files/2018-07/documents/2015_smm_msw_factsheet_07242018_fnl_508_002.pdf

U.S. Environmental Protection Agency (EPA). (2018b). Wastes – Non-Hazardous Waste - Municipal Solid Waste Landfills. Last updated September 13, 2018. Available at: https://www.epa.gov/landfills/municipal-solid-waste-landfills#regs

15. Attachments:

Appendix 1: Biocol BS 3010 Material Safety Data Sheet (MSDS)

CONFIDENTIAL Appendix 2: Market Volume Projections and Associated Estimates (Separate Enclosure)

Appendix 1

Biocol BS 3010 Material Safety Data Sheet (MSDS)

Biocol BS3010

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

1.1 Product identifier: Biocol BS3010

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

Relevant uses: Cork and/or rubber agglomeration

Uses advised against: All uses not specified in this section or in section 7.3

1.3 Details of the supplier of the safety data sheet:

Resibras – Companhia Portuguesa de Resinas para Abrasivos, S.A.
Parque Industrial de Carrascas
2950-402 Palmela - Setúbal - Portugal
Phone.: +351212389870 -
Fax: +351212380737
cpresinas@resibras.pt
www.resibras.pt

1.4 Emergency telephone number: Business days; 9h-18h: +351 212389870

SECTION 2: HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture:

CLP Regulation (EC) nº 1272/2008:

Classification of this product has been carried out in accordance with CLP Regulation (EC) nº 1272/2008.

Resp. Sens. 1: Sensitisation, respiratory, Category 1, H334

2.2 Label elements:

CLP Regulation (EC) nº 1272/2008:

Danger

Hazard statements:

Resp. Sens. 1: H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled

Precautionary statements:

P261: Avoid breathing dust/fume/gas/mist/vapours/spray
P304+P340: IF INHALED: Remove person to fresh air and keep comfortable for breathing
P501: Dispose of contents and / or containers in accordance with regulations on hazardous waste or packaging and packaging waste respectively

Supplementary information:

EUH204: Contains isocyanates. May produce an allergic reaction

Substances that contribute to the classification

Toluene Diisocyanate

2.3 Other hazards:

This product doesn't meet the criteria PBT/mPmB according Annex XIII of REACH Regulation.
The odour is not an adequate warning of the presence of danger concentrations in the air. Odour threshold of 0,4 to 2,14 ppm.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substance:

Non-applicable

3.2 Mixture:

Chemical description: Polyurethane prepolymer

Components:

In accordance with Annex II of Regulation (EC) nº1907/2006 (point 3), the product contains:

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SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS (continue)

Identification	Chemical name/Classification		Concentration
CAS: 26471-62-5 EC: 247-722-4 Index: 615-006-00-4 REACH: 01-2119454791-34-XXXX	**Toluene Diisocyanate**	Self-classified	**<1 %**
	Regulation 1272/2008	Acute Tox. 1: H330; Aquatic Chronic 3: H412; Carc. 2: H351; Eye Irrit. 2: H319; Resp. Sens. 1: H334; Skin Irrit. 2: H315; Skin Sens. 1: H317; STOT SE 3: H335 - Danger	

To obtain more information on the risk of the substances consult sections 8, 11, 12, 15 and 16.

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures:

The symptoms resulting from intoxication can appear after exposure, therefore, in case of doubt, seek medical attention for direct exposure to the chemical product or persistent discomfort, showing the SDS of this product.

By inhalation:

Remove the person affected from the area of exposure, provide with fresh air and keep at rest. In serious cases such as cardiorespiratory failure, artificial resuscitation techniques will be necessary (mouth to mouth resuscitation, cardiac massage, oxygen supply, etc.) requiring immediate medical assistance.

By skin contact:

This product is not classified as hazardous when in contact with the skin. However, in case of skin contact it is recommended to remove contaminated clothes and shoes, rinse the skin or shower the person affected if necessary thoroughly with cold water and neutral soap. In case of serious reaction consult a doctor.

By eye contact:

Rinse eyes thoroughly with water for at least 15 minutes. If the injured person uses contact lenses, these should be removed unless they are stuck to the eyes, as this could cause further damage. In all cases, after cleaning, a doctor should be consulted as quickly as possible with the SDS of the product.

By ingestion/aspiration:

Do not induce vomiting, but if it does happen keep the head down to avoid aspiration. Keep the person affected at rest. Rinse out the mouth and throat, as they may have been affected during ingestion.

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

Acute and delayed effects are indicated in sections 2 and 11.

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

The product irritates the airways and is a potential skin and airway sensitizer.
The treatment of acute irritation or bronchi narrowing is first symptomatic (decontamination, vital functions).
It's not known a specific antidote. Depending on the degree of exposure and disorder, can be necessary a medical treatment for a longer period of time.

SECTION 5: FIREFIGHTING MEASURES

5.1 Extinguishing media:

Product is non-flammable under normal conditions of storage, manipulation and use. In the case of inflammation as a result of improper manipulation, storage or use preferably use polyvalent powder extinguishers (ABC powder), in accordance with the Regulation on fire protection systems. IT IS NOT RECOMMENDED to use tap water as an extinguishing agent.

5.2 Special hazards arising from the substance or mixture:

As a result of combustion or thermal decomposition reactive sub-products are created that can become highly toxic and, consequently, can present a serious health risk.

5.3 Advice for firefighters:

Depending on the magnitude of the fire it may be necessary to use full protective clothing and individual respiratory equipment. Minimum emergency facilities and equipment should be available (fire blankets, portable first aid kit,...) in accordance with Directive 89/654/EC.

Additional provisions:

Act in accordance with the Internal Emergency Plan and the Information Sheets on actions to take after an accident or other emergencies. Destroy any source of ignition. In case of fire, refrigerate the storage containers and tanks for products susceptible to inflammation, explosion or BLEVE as a result of high temperatures. Avoid spillage of the products used to extinguish the fire into an aqueous medium.

SECTION 6: ACCIDENTAL RELEASE MEASURES

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SECTION 6: ACCIDENTAL RELEASE MEASURES (continue)

6.1 Personal precautions, protective equipment and emergency procedures:

Isolate leaks provided that there is no additional risk for the people performing this task. Personal protection equipment must be used against potential contact with the spilt product (See section 8). Evacuate the area and keep out those who do not have protection.

6.2 Environmental precautions:

Avoid spillage into an aqueous medium as it contains substances potentially dangerous for this. Contain the product absorbed in hermetically sealed containers. In the case of serious spillage into an aqueous medium notify the relevant authority.

6.3 Methods and material for containment and cleaning up:

It is recommended:

Absorb the spillage using sand or inert absorbent and move it to a safe place. Do not absorb in sawdust or other combustible absorbents. For any concern related to disposal consult section 13.

6.4 Reference to other sections:

See sections 8 and 13.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling:

A.- Precautions for safe manipulation

Comply with the current legislation concerning the prevention of industrial risks. Keep containers hermetically sealed. Control spills and residues, destroying them with safe methods (section 6). Avoid leakages from the container. Maintain order and cleanliness where dangerous products are used.

B.- Technical recommendations for the prevention of fires and explosions

Product is non-flammable under normal conditions of storage, manipulation and use. It is recommended to transfer at slow speeds to avoid the generation of electrostatic charges that can affect flammable products. Consult section 10 for information on conditions and materials that should be avoided.

C.- Technical recommendations to prevent ergonomic and toxicological risks

Do not eat or drink during the process, washing hands afterwards with suitable cleaning products.

D.- Technical recommendations to prevent environmental risks

It is recommended to have absorbent material available at close proximity to the product (See subsection 6.3)

7.2 Conditions for safe storage, including any incompatibilities:

A.- Technical measures for storage

Store in a cool, dry, well-ventilated location

B.- General conditions for storage

Avoid sources of heat, radiation, static electricity and contact with food. For additional information see subsection 10.5

Other information:

Protect the product against moisture contact. In case of moisture contact the product releases CO2, and if hermetically closed there is a danger of pressure increase.
Avoid the contact with water, acids, alcohols, caustic soda and aminic catalysts
Suitable packaging materials are: carbon steel (iron), high density polyethylene (HDPE), low density polyethylene (LDPE), tin (tinplate) and stainless steel 1.4306 (V2A).

7.3 Specific end use(s):

Except for the instructions already specified it is not necessary to provide any special recommendation regarding the uses of this product.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters:

Substances whose occupational exposure limits have to be monitored in the work environment

Toluene Diisocyanate, CAS: 26471-62-5 EC: 247-722-4; TLV-TWA: 0.005 ppm; TLV-STEL: 0.02 ppm; (Values for 2015)

DNEL (Workers):

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SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION (continue)

Identification		Short exposure		Long exposure	
		Systemic	Local	Systemic	Local
Toluene Diisocyanate	Oral	Non-applicable	Non-applicable	Non-applicable	Non-applicable
CAS: 26471-62-5	Dermal	Non-applicable	Non-applicable	Non-applicable	Non-applicable
EC: 247-722-4	Inhalation	0,14 mg/m³	0,14 mg/m³	0,035 mg/m³	0,035 mg/m³

DNEL (General population):

Non-applicable

PNEC:

Identification				
Toluene Diisocyanate	STP	1 mg/L	Fresh water	0,0125 mg/L
CAS: 26471-62-5	Soil	1 mg/kg	Marine water	0,00125 mg/L
EC: 247-722-4	Intermittent	0,125 mg/L	Sediment (Fresh water)	Non-applicable
	Oral	Non-applicable	Sediment (Marine water)	Non-applicable

8.2 Exposure controls:

A.- General security and hygiene measures in the work place

As a preventative measure it is recommended to use basic Personal Protection Equipment, with the corresponding <<CE marking>> in accordance with Directive 89/686/EC. For more information on Personal Protection Equipment (storage, use, cleaning, maintenance, class of protection,...) consult the information leaflet provided by the manufacturer. For more information see subsection 7.1.
All information contained herein is a recommendation which needs some specification from the labour risk prevention services as it is not known whether the company has additional measures at its disposal.

B.- Respiratory protection

Pictogram	PPE	Labelling	CEN Standard	Remarks
 Mandatory respiratory tract protection	Filter mask for gases and vapours	CE CAT III	EN 405:2001+A1:2009	Replace when there is a taste or smell of the contaminant inside the face mask. If the contaminant comes with warnings it is recommended to use isolation equipment.

C.- Specific protection for the hands

Pictogram	PPE	Labelling	CEN Standard	Remarks
 Mandatory hand protection	Chemical protective gloves	CE CAT I	EN 420:2003+A1:2009	Replace the gloves at any sign of deterioration.

D.- Ocular and facial protection

Pictogram	PPE	Labelling	CEN Standard	Remarks
 Mandatory face protection	Panoramic glasses against liquid splash	CE CAT II	EN 166:2001 EN 172:1994/A1:2000 EN 172:1994/A2:2001 EN ISO 4007:2012	Clean daily and disinfect periodically according to the manufacturer´s instructions. Use if there is a risk of splashing.

E.- Bodily protection

Pictogram	PPE	Labelling	CEN Standard	Remarks
	Work clothing	CE CAT I	EN ISO 13688:2013	For professional use only.
	Anti-slip work shoes	CE CAT II	EN ISO 20347:2012 EN ISO 20344:2011	None

F.- Additional emergency measures

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SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION (continue)

Emergency measure	Standards	Emergency measure	Standards
 Emergency shower	ANSI Z358-1 ISO 3864-1:2002	 Eyewash stations	DIN 12 899 ISO 3864-1:2002

Environmental exposure controls:

In accordance with the community legislation for the protection of the environment it is recommended to avoid environmental spillage of both the product and its container. For additional information see subsection 7.1.D

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties:

For complete information see the product datasheet.

Appearance:

Physical state at 20 ºC:	Liquid
Appearance:	Viscous
Color:	Yellow
Odor:	Characteristic

Volatility:

Boiling point at atmospheric pressure:	250 ºC
Vapour pressure at 25 ºC:	2 Pa
Vapour pressure at 50 ºC:	17 Pa (0 kPa)
Evaporation rate at 25 ºC:	Non-applicable *

Product description:

Density at 25 ºC:	1040 kg/m³
Relative density at 25 ºC:	1,04
Dynamic viscosity at 25 ºC:	6000 cP
Kinematic viscosity at 25 ºC:	Non-applicable *
Kinematic viscosity at 40 ºC:	Non-applicable *
Concentration:	Non-applicable *
pH:	Non-applicable *
Vapour density at 25 ºC:	Non-applicable *
Partition coefficient n-octanol/water 25 ºC:	Non-applicable *
Solubility in water at 25 ºC:	Non-applicable *
Solubility properties:	Non-applicable *
Decomposition temperature:	Non-applicable *
Melting point/freezing point:	Non-applicable *

Flammability:

Flash Point:	Non Flammable (>60 ºC)
Autoignition temperature:	620 ºC
Lower flammability limit:	Non-applicable *
Upper flammability limit:	Non-applicable *

9.2 Other information:

Surface tension at 25 ºC:	Non-applicable *
Refraction index:	Non-applicable *

The values in the above table can not be considered specifications. Specification values are in the technical data sheet of the product.

*Not relevant due to the nature of the product, not providing information property of its hazards.

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SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity:

No hazardous reactions are expected if the following technical instructions storage of chemicals. See section 7.

10.2 Chemical stability:

Chemically stable under the conditions of storage, handling and use.

10.3 Possibility of hazardous reactions:

Under the specified conditions, hazardous reactions that lead to excessive temperatures or pressure are not expected.

10.4 Conditions to avoid:

Applicable for handling and storage at room temperature:

Shock and friction	Contact with air	Increase in temperature	Sunlight	Humidity
Not applicable	Not applicable	Avoid direct impact	Not applicable	Avoid direct impact

10.5 Incompatible materials:

Acids	Water	Combustive materials	Combustible materials	Others
Precaution	Avoid direct impact	Avoid direct impact	Not applicable	Avoid alkalines, heavy metals, reducing agents, peroxide accelerating agents

10.6 Hazardous decomposition products:

See subsection 10.3, 10.4 and 10.5 to find out the specific decomposition products. Depending on the decomposition conditions, complex mixtures of chemical substances can be released: carbon dioxide (CO2), carbon monoxide and other organic compounds.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects:

The experimental information related to the toxicological properties of the product itself is not available

Dangerous health implications:

In case of exposure that is repetitive, prolonged or at concentrations higher than recommended by the occupational exposure limits, it may result in adverse effects on health depending on the means of exposure:

A.- Ingestion:

- Acute toxicity: Based on available data, the classification criteria are not met, as it does not contain substances classified as dangerous for consumption. For more information see section 3.
- Corrosivity/Irritability: Based on available data, the classification criteria are not met, however, it contains substances classified as dangerous for consumption. For more information see section 3.

B- Inhalation:

- Acute toxicity: Based on available data, the classification criteria are not met, however, it contains substances classified as dangerous for inhalation. For more information see section 3.
- Corrosivity/Irritability: Based on available data, the classification criteria are not met, however, it contains substances classified as dangerous for inhalation. For more information see section 3.

C- Contact with the skin and the eyes:

- Contact with the skin: Based on available data, the classification criteria are not met, however, it contains substances classified as dangerous for skin contact. For more information see section 3.
- Contact with the eyes: Based on available data, the classification criteria are not met, however, it contains substances classified as dangerous for skin contact. For more information see section 3.

D- CMR effects (carcinogenicity, mutagenicity and toxicity to reproduction):

- Carcinogenicity: Based on available data, the classification criteria are not met, however, it contains substances classified as dangerous with carcinogenic effects. For more information see section 3.
- Mutagenicity: Based on available data, the classification criteria are not met, as it does not contain substances classified as dangerous for this effect. For more information see section 3.
- Reproductive toxicity: Based on available data, the classification criteria are not met, as it does not contain substances classified as dangerous for this effect. For more information see section 3.

E- Sensitizing effects:

- Respiratory: Prolonged exposure can result in specific respiratory hypersensitivity.
- Cutaneous: Based on available data, the classification criteria are not met, however, it contains substances classified as dangerous with sensibilizising effects. For more information see section 3.

F- Specific target organ toxicity (STOT)-time exposure:

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SECTION 11: TOXICOLOGICAL INFORMATION (continue)

Based on available data, the classification criteria are not met, however, it contains substances classified as dangerous for inhalation. For more information see section 3.

G- Specific target organ toxicity (STOT)-repeated exposure:

- Specific target organ toxicity (STOT)-repeated exposure: Based on available data, the classification criteria are not met, as it does not contain substances classified as dangerous for this effect. For more information see section 3.
- Skin: Based on available data, the classification criteria are not met, as it does not contain substances classified as dangerous for this effect. For more information see section 3.

H- Aspiration hazard:

Based on available data, the classification criteria are not met, as it does not contain substances classified as dangerous for this effect. For more information see section 3.

Other information:

Non-applicable

Specific toxicology information on the substances:

Identification	Acute toxicity		Genus
Toluene Diisocyanate	LD50 oral	4130 mg/kg	Rat Male
CAS: 26471-62-5	LD50 dermal	>9400 mg/kg bw	Rabbit
EC: 247-722-4	LC50 inhalation	0,248mg/L (1 h)	Rat M/F

SECTION 12: ECOLOGICAL INFORMATION

The experimental information related to the eco-toxicological properties of the product itself is not available

12.1 Toxicity:

Identification	Acute toxicity		Specie	Genus
Toluene Diisocyanate	LC50	133 mg/L (96 h)	Oncorhynchus mykiss	Fish
CAS: 26471-62-5	EC50	12,5 mg/L (48 h)	Daphnia magna	Crustacean
EC: 247-722-4	EC50	4300 mg/L (96 h)	Chlorella vulgaris	Algae

12.2 Persistence and degradability:

hardly biodegradable.

12.3 Bioaccumulative potential:

It is not expected to accumulate in organisms

12.4 Mobility in soil:

The aquatic and terrestrial mobility is limited because of the reaction with water, forming predominantly insoluble polyureas

12.5 Results of PBT and vPvB assessment:

Not considered persitent, biocomulative or toxic (PBT). Not considered very persistent or very biocomulative (vPvB).

12.6 Other adverse effects:

The product is not listed in Regulation EC Nº 2037/2000 regarding on substances depleting the ozone layer.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods:

Type of waste (Regulation (EU) No 1357/2014):

HP6 Acute Toxicity

Waste management (disposal and evaluation):

Consult the authorized waste service manager on the assessment and disposal operations in accordance with Annex 1 and Annex 2 (Directive 2008/98/EC). As under 15 01 (2014/955/EC) of the code and in case the container has been in direct contact with the product, it will be processed the same way as the actual product. Otherwise, it will be processed as non-dangerous residue. We do not recommended disposal down the drain. See paragraph 6.2.

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SECTION 13: DISPOSAL CONSIDERATIONS (continue)

Regulations related to waste management:

In accordance with Annex II of Regulation (EC) nº1907/2006 (REACH) the community or state provisions related to waste management are stated
Community legislation: Directive 2008/98/EC, 2014/955/EU, Regulation (EU) No 1357/2014

SECTION 14: TRANSPORT INFORMATION

Transport of dangerous goods by land:

With regard to ADR 2015 and RID 2015:

14.1	**UN number:**	Non-applicable
14.2	**UN proper shipping name:**	Non-applicable
14.3	**Transport hazard class(es):**	Non-applicable
	Labels:	Non-applicable
14.4	**Packing group:**	Non-applicable
14.5	**Dangerous for the environment:**	No
14.6	**Special precautions for user**	
	Special regulations:	Non-applicable
	Tunnel restriction code:	Non-applicable
	Physico-Chemical properties:	see section 9
	Limited quantities:	Non-applicable
14.7	**Transport in bulk according to Annex II of Marpol and the IBC Code:**	Non-applicable

Transport of dangerous goods by sea:

With regard to IMDG 37-14:

14.1	**UN number:**	Non-applicable
14.2	**UN proper shipping name:**	Non-applicable
14.3	**Transport hazard class(es):**	Non-applicable
	Labels:	Non-applicable
14.4	**Packing group:**	Non-applicable
14.5	**Dangerous for the environment:**	No
14.6	**Special precautions for user**	
	Special regulations:	Non-applicable
	EmS Codes:	
	Physico-Chemical properties:	see section 9
	Limited quantities:	Non-applicable
14.7	**Transport in bulk according to Annex II of Marpol and the IBC Code:**	Non-applicable

Transport of dangerous goods by air:

With regard to IATA/ICAO 2015:

14.1	**UN number:**	Non-applicable
14.2	**UN proper shipping name:**	Non-applicable
14.3	**Transport hazard class(es):**	Non-applicable
	Labels:	Non-applicable
14.4	**Packing group:**	Non-applicable
14.5	**Dangerous for the environment:**	No
14.6	**Special precautions for user**	
	Physico-Chemical properties:	see section 9
14.7	**Transport in bulk according to Annex II of Marpol and the IBC Code:**	Non-applicable

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SECTION 15: REGULATORY INFORMATION

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

Candidate substances for authorisation under the Regulation (EC) 1907/2006 (REACH): Non-applicable

Substances included in Annex XIV of REACH ("Authorisation List") and sunset date: Non-applicable

Regulation (EC) 1005/2009, about substances that deplete the ozone layer: Non-applicable

Active substances for which a decision of non-inclusion onto Annex I (Regulation (EU) No 528/2012): Non-applicable

REGULATION (EU) No 649/2012, in relation to the import and export of hazardous chemical products: Non-applicable

Limitations to commercialisation and the use of certain dangerous substances and mixtures (Annex XVII, REACH):

Non-applicable

Specific provisions in terms of protecting people or the environment:

It is recommended to use the information included in this safety data sheet as data used in a risk evaluation of the local circumstances in order to establish the necessary risk prevention measures for the manipulation, use, storage and disposal of this product.

Other legislation:

The product could be affected by sectorial legislation

15.2 Chemical safety assessment:

The supplier has not carried out evaluation of chemical safety.

SECTION 16: OTHER INFORMATION

Legislation related to safety data sheets:

This safety data sheet has been designed in accordance with ANNEX II-Guide to the compilation of safety data sheets of Regulation (EC) Nº 1907/2006 (Regulation (EU) Nº 453/2010, Regulation (EC) Nº 2015/830)

Modifications related to the previous security card which concerns the ways of managing risks. :

Section 1.2, relevant uses.

Texts of the legislative phrases mentioned in section 2:

H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled

Texts of the legislative phrases mentioned in section 3:

The phrases indicated do not refer to the product itself; they are present merely for informative purposes and refer to the individual components which appear in section 3

CLP Regulation (EC) nº 1272/2008:

Acute Tox. 1: H330 - Fatal if inhaled
Aquatic Chronic 3: H412 - Harmful to aquatic life with long lasting effects
Carc. 2: H351 - Suspected of causing cancer
Eye Irrit. 2: H319 - Causes serious eye irritation
Resp. Sens. 1: H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled
Skin Irrit. 2: H315 - Causes skin irritation
Skin Sens. 1: H317 - May cause an allergic skin reaction
STOT SE 3: H335 - May cause respiratory irritation

Classification procedure:

Resp. Sens. 1: Calculation method

Advice related to training:

Minimal training is recommended to prevent industrial risks for staff using this product, in order to facilitate their comprehension and interpretation of this safety data sheet, as well as the label on the product.

Principal bibliographical sources:

http://esis.jrc.ec.europa.eu
http://echa.europa.eu
http://eur-lex.europa.eu

Abbreviations and acronyms:

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SECTION 16: OTHER INFORMATION (continue)

- ADR: European agreement concerning the international carriage of dangerous goods by road
-IMDG: International maritime dangerous goods code
-IATA: International Air Transport Association
-ICAO: International Civil Aviation Organisation
-COD: Chemical Oxygen Demand
-BOD5: 5-day biochemical oxygen demand
-BCF: Bioconcentration factor
-LD50: Lethal Dose 50
-CL50: Lethal Concentration 50
-EC50: Effective concentration 50
-Log-POW: Octanol–water partition coefficient
-Koc: Partition coefficient of organic carbon

- END OF SAFETY DATA SHEET -