

USUAL PRODUCT/ ARTICLE REGULATORY & SAFETY REVIEW

DOOR BUMPER -CLEAR

Product name	Door Bumper - Clear
Customer	Strongest Home
Biorius code	STHO-0002
Usual product category	Article
Administrative information	<u>Supplier:</u> Strongest Home <u>Manufacturer:</u> EWING Entreprises CO., Limited Room 208, building 56, JinShanGu YiKu, Creative Park, DongYi road, Panyu District Guangzhou city, GuangDong Province, CHINA
Unique Formula Identifier	Not required
Distribution country	EU

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1. RAW MATERIALS / SUBSTANCE COMPOSITION

Table 1: Raw material and substance composition

Raw material	SUBSTANCE	CAS	% SUBSTANCE IN RAW MATERIAL	% SUBSTANCE IN FORMULA	HAZARD CLASSIFICATIONS
PVC « Polyurethane prepolymer A/B »	Poloxalene	9003-11-6	79.15%	79.15%	According to the Raw material' SDS provided: Not classified
	4,4-methylenediphenyl diisocyanate	101-68-8	10.56%	10.56%	According to the Raw material' SDS provided: Resp. Sens. 1, H334 Carc.2, H351 STOT RE 2, H373 Acute Tox. 4, H332 Skin irrit. 2, H315 Eye irrit 2. H319 Skin Sens. 1, H317 STOT SE 3, H335
	Bis(2-ethylhexyl) terephthalate	6422-86-2	10.16%	10.16%	According to the Raw material' SDS provided: Not classified
	Bismuth citrate	813-93-4	0.13%	0.13%	According to the Raw material' SDS provided: Not classified

2. PRODUCT & SUBSTANCE REGULATORY COMPLIANCE

2.1.CLP classification

According to Safety Data Sheet (SDS) provided by the manufacturer, the mixture on liquid form is classified as [1]:

Resp. Sens. 1, H334
Carc.2, H351
STOT RE 2, H373
Skin irrit. 2, H315
Eye irrit. 2, H319
Skin Sens. 1, H317
STOT SE 3, H335

However, the hazard classification of the substance is based on the liquid form. No hazard is expected on the product as an inert and solid article. From the available information, the final product is expected as:

- not classified

2.2.Poison Centre Notifications

The final product is expected as: not classified for human health. As such, notification to poison centre or UFI are not required.

2.3.Substances of Very High Concern (SVHC)

The test report [2] provided by the producer states the absence of SVHC substance in the product.

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2.4.Restriction list

The substance 4,4-methylenediphenyl diisocyanate (CAS N° 101-68-8) is included in the restriction list for some uses.

However, the restrictions are not applicable to the final product (as a solid article) The restrictions are only applicable to the said substance on its own, as a constituent in other substances or in mixtures for industrial and professional uses ([503ac424-3bcb-137b-9247-09e41eb6dd5a \(europa.eu\)](https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:503ac424-3bcb-137b-9247-09e41eb6dd5a)).

2.5.Waste Framework Directive (WFD)

According to the provided report [2], no SVHC substances or substances included in the REACH Candidate list is expected to be found in the product. No SCIP notification is required.

In the case that the product contains these substances at a threshold higher than 0.1% by weight, a notification in SCIP (Substances of Concern In articles as such or in complex objects (Products)) database must be performed.

3. Risk Assessment

According to General Product Safety Directive (EC 95/2001) and European Detergent Regulation (EC 648/2004), the detergent product is assessed for consumer health risk, using the REACH method (ECHA R. 8 Guidance on information requirements and chemical safety assessment).

3.1.Hazards

The human health hazards (from the Safety Data Sheets information) associated per raw materials are summarised in the table below.

Table 2: Substance hazards

SUBSTANCE	CAS	% SUBSTANCE IN FORMULA	HAZARD CLASSIFICATIONS
Poloxalene	9003-11-6	79.15%	According to the Raw material' SDS provided: Not classified
4,4-methylenediphenyl diisocyanate	101-68-8	10.56%	According to the Raw material' SDS provided: Resp. Sens. 1, H334 Carc.2, H351 STOT RE 2, H373 Acute Tox. 4, H332 Skin irrit. 2, H315 Eye irrit.2 . H319 Skin Sens. 1, H317 STOT SE 3, H335
Bis(2-ethylhexyl) terephthalate	6422-86-2	10.16%	According to the Raw material' SDS provided: Not classified
Bismuth citrate	813-93-4	0.13%	According to the Raw material' SDS provided: Not classified

3.2.Exposure

According to the manufacturer information, the product is intended to be applied on doors. The exposure is considered as exclusively skin exposure, only during a very short time (manipulation of the product to be applied on the door)

No systemic exposure, no oral or eye exposure is expected under the normal conditions of use.

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3.3. Risk characterization

3.3.1. Systemic quantitative risk assessment

According to the substance hazard classification, the substance 4,4-methylenediphenyl diisocyanate (CAS N° 101-68-8) is substance of concern for systemic toxicity. However, the hazard classification of the substance is based on the liquid form of the substance. In this product, the product was used as inert (solid form). No hazard is expected from this solid and inert form of the substance. Therefore, under normal condition of use, the systemic toxicity risk is considered as controlled.

3.3.2. Local toxicity risk assessment

3.3.2.1. Eye irritation

The substance 4,4-methylenediphenyl diisocyanate (CAS N° 101-68-8) is classified as eye irrit. 2, H319. However, the hazard classification of the substance is based on the liquid form of the substance. In this product, the product was used as inert (solid form). No hazard is expected from this solid and inert form of the substance. The eye irritation risk is considered as controlled under the normal condition of use.

3.3.2.2. Skin irritation

The substance 4,4-methylenediphenyl diisocyanate (CAS N° 101-68-8) is classified as skin irrit. 2, H315. However, the hazard classification of the substance is based on the liquid form of the substance. In this product, the product was used as inert (solid form). No hazard is expected from this solid and inert form of the substance. The skin irritation risk is considered as controlled under the normal condition of use.

3.3.2.3. Acute oral toxicity

The substance 4,4-methylenediphenyl diisocyanate (CAS N° 101-68-8) is classified as acute tox. 4, H332. However, the hazard classification of the substance is based on the liquid form of the substance. In this product, the product was used as inert (solid form). No hazard is expected from this solid and inert form of the substance. The acute oral risk is considered as controlled under the normal condition of use.

3.3.2.4. Skin sensitization

The substance 4,4-methylenediphenyl diisocyanate (CAS N° 101-68-8) is classified as skin sens. 1, H317. However, the hazard classification of the substance is based on the liquid form of the substance. In this product, the product was used as inert (solid form). No hazard is expected from this solid and inert form of the substance. The skin sensitization risk is considered as controlled under the normal condition of use.

4. CONCLUSION

The product "Door Bumper- CLEAR" was assessed for compliance to the General Product Safety Directive EC 95/2001.

Under the strict normal condition of use, the human health risk is considered as controlled.

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5. LABELLING RECOMMENDATIONS

CLP EC 1272/2008 REGULATION - USUAL PRODUCT & Waste Directive Framework 98/2008

MANDATORY INFORMATION LABELS	Additional REMARKS/ADVICE
Name, address, phone number of the supplier & EU mandatory person	The complete address of the supplier and EU mandatory person must appear on the label.
Product identification (as identified in the SDS)	Door Bumper - Clear
Nominal content	must be labelled
Product function	must be labelled
Instruction for use	The instructions of use must be labelled or included in the product (leaflet as example)
Hazard substance list	The product is not classified; thus, it is not required here
Symbols (CLP)	The product is not classified; thus, it is not required here
Signal word	The product is not classified; thus, it is not required here
Hazard statements	The product is not classified; thus, it is not required here
Precautionary statements	The product is not classified; thus, it is not required here
EUH 208 Phrases	The product is not classified; thus, it is not required here
Unique Formula Identifier (ie UFI)	The product is not classified; thus, it is not required here
Child Resistance Fastening	The product is not classified; thus, it is not required here
Tactical Warnings of danger	The product is not classified; thus, it is not required here
Additional statement	Made in China Fabriqué en Chine

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6. CONCLUSION

The product “Door Bumper - Clear” was assessed for compliance to the CLP regulation and labelling.

The product must be labelled according to CLP EC 1272/2008 REGULATION - USUAL PRODUCT & Waste Directive Framework 98/2008 as indicated at point 5 of the present report.

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This study is a supporting document aimed at verifying if each substance complies with the Usual Product Regulation EC 648/2004 and with the General Product Safety Directive 2001/91/EC.

Date: September 5, 2023

7. REFERENCES

1. PDF Door Bumper - clear / documentation provided by the producer Ewing Enterprise Co. Ltd
2. SGS - Test report SVHC - N° CANREC23001846201 - 21/04/2023
3. <https://www.echa.europa.eu/fr/information-on-chemicals>