# USUAL PRODUCT/ ARTICLE REGULATORY & SAFETY REVIEW
# DOOR STOPPER

| | |
|---|---|
| **Product name** | Door Stopper |
| **Customer** | Strongest Home |
| **Biorius code** | STHO-0001 |
| **Usual product category** | Article |
| **Administrative information** | Supplier:<br>Strongest Home<br><br>Manufacturer:<br>EWING Entreprises CO., Limited<br>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 |

TABLE OF CONTENT



TABLES AND FIGURES

# 1. RAW MATERIALS / SUBSTANCE COMPOSITION

Table 1: Raw material and substance composition

| SUBSTANCE | CAS | % SUBSTANCE IN RAW MATERIAL | % SUBSTANCE IN FORMULA | HAZARD CLASSIFICATIONS |
|---|---|---|---|---|
| **Zinc alloy** | 7440-66-6 | 100% | 70% | According to the information provided: not classified. |
| **Steel** | 7439-89-6 | 100% | 10% | |
| **Polyurethane** | 51852-81-4 | 88% | 20% | |
| **Polyethylene terephtalate** | 250385-59-9 | 2% | | |
| **Thermoplastic polyuretahnes** | 226219-46-1 | 1% | | |
| **Terylene** | 42084-32-3 | 9% | | |

# 2. PRODUCT & SUBSTANCE REGULATORY COMPLIANCE

## 2.1. Hazard classification

According to the information provided by the manufacturer [1]; the finished product is classified as

- Not classified

## 2.2. Poison Centre Notification

The product is not classified for human health. The product does not require notification to poison centre or UFI.

## 2.3. Substances of Very High Concern (SVHC)

The test report [1] provided by the producer states the absence of SVHC substance in the product. However, the full study report stating the name of the assessed product must be provided.

## 2.4. Restriction list

There is no substance listed in the restriction List. A REACH certification or statement of absence of the listed substances should be provided.

## 2.5. Waste Framework Directive (WFD)

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), the product is assessed for consumer health risk, using the REACh method (ECHA R. 8 Guidance on information requirements and chemical safety assessment).

### 3.1.1. 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 |
|---|---|---|---|
| **Zinc alloy** | 7440-66-6 | 70% | Not hazardous |
| **Steel** | 7439-89-6 | 10% | Not hazardous |
| **Polyurethane** | 51852-81-4 | 17.6% | Not hazardous |
| **Polyethylene terephtalate** | 250385-59-9 | 0.4% | Not hazardous |
| **Thermoplastic polyuretahnes** | 226219-46-1 | 0.2% | Not hazardous |
| **Terylene** | 42084-32-3 | 1.8% | Not hazardous |

### 3.1.2. Exposure

According to the manufacturer information, the product is intended to be applied underneath 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.

### 3.1.3. Risk characterization

#### 3.1.3.1. Systemic quantitative risk assessment

According to the substance hazard classification, there is NO substance of concern for systemic toxicity.
Therefore, under normal condition of use, the systemic toxicity risk is considered as controlled.

#### 3.1.3.2. Local toxicity risk assessment

##### 3.1.3.2.1. Eye irritation

There is no hazardous substance in the product. The eye irritation risk is considered as controlled under the normal condition of use.

##### 3.1.3.2.2. Skin irritation

There is no hazardous substance in the product. The skin irritation risk is considered as controlled under the normal condition of use.

##### 3.1.3.2.3. Acute oral toxicity

There is no hazardous substance in the product. The acute oral risk is considered as controlled under the normal condition of use.

##### 3.1.3.2.4. Skin sensitization

There is no hazardous substance in the product. The skin sensitization risk is considered as controlled under the normal condition of use.

## 4. CONCLUSION

The product “Door Stopper” 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. However, the full study report of Substances of Very High Concern (SVHC) should be available.

## 5. LABELLING RECOMMENDATIONS

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

| MANDATROY INFORMATION LABELS | Additionnal 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 Stopper |
| **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<br>Fabriqué en Chine |
| Concern (SVHC) | Not required as no SVHC substance according to the provided attestation |

## 6. CONCLUSION

The product “Door Stopper” 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.

## Disclaimer

Biorius sprl is liable for the quality of its regulatory work based on the information supplied by the Client. If such information supplied to Biorius sprl is wrong or incomplete, then Biorius sprl is not responsible and the Client hereby indemnifies and holds harmless Biorius sprl and each of its officers, employees and agents against any and all liabilities, costs and expenses incurred in connection with performance or services.

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 Stopper documentation provided by the producer Ewing Enterprise Co. Ltd including: SGS – Test report SVHC – N°CANML2105872301 – 20/04/2021
2. https://www.echa.europa.eu/fr/information-on-chemicals